

OPERATION/SERVICE MANUAL

IQmark[™]
Digital Spirometer

Version 6.1

Accessed through

IQmark[™]
Diagnostic Workstation

BRENTWOOD[®]
by **MIDMARK**[®]

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Physician's Responsibility

The IQmark Digital Spirometer can provide test interpretations if the user enables the Auto Interpretation feature. These interpretations are for the exclusive use of licensed physicians or personnel under their direct supervision. The suggested interpretation and the numerical and graphical results should be examined with respect to the patient's overall clinical condition. Final analysis should always be determined and verified by a physician.

Spirometry is an effort dependent test. Proper administration of the test is the physician's responsibility, as is making a diagnosis, obtaining expert opinions on the results, and implementing the correct treatment, if indicated.

FOREWORD

A Word of Thanks

Thank you for purchasing the Brentwood IQmark Digital Spirometer and IQmark Diagnostic Workstation. Brentwood Medical Technology has used the latest microelectronic and computer software technology to develop a fast, efficient, and accurate spirometry system. We trust our product will enable you to use office-based spirometry tests to diagnose and enhance your patient's pulmonary health.

Brentwood Medical Technology provides a range of diagnostic products, including ECG and Holter, which are accessed using the Diagnostic Workstation program.

We believe you will be pleased with the user-friendly operation of our product and with your results. As your partner in patient care, we look forward to working with you in the coming years as we develop even more sophisticated diagnostic technology for the medical field. Your thoughts, questions and comments about our product and direction are welcomed.

Brentwood Medical Technology PH (800) 624-8950 or (310) 530-5955

Year 2000 Compliance

This medical software product has been designed to be Year 2000 Compliant, provided that the computer where this product is installed is Year 2000 Compliant. To find out if your computer is Year 2000 Compliant, contact the computer manufacturer.

The IQmark Digital Spirometer uses the current date from the computer and the patient's birth date (entered by the user) to calculate the patient's age. Since the Spirometer's equations and interpretive analysis use the patient's age to produce appropriate diagnostic statements, it is important that your computer's current date is accurate. Contact your system administrator if your computer's date is incorrect.

Notice

The information in this operation manual is subject to change without notice.

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Device Labeling Information

Indications For Use

The IQmark Digital Spirometer is indicated for use with male/female adult patients and male/female pediatric patients to evaluate, assess, describe, measure, or monitor the status of pulmonary health, diseases, or conditions.

Intended Use

The IQmark Digital Spirometer is intended for use as a prescription-use-only clinical diagnostic spirometer for pulmonary function evaluation and data management. The spirometer is for use in hospitals or physician/clinician offices.

Contraindications

The Disposable Pneumotach Mouthpieces are clean but not sterile and should not be placed over open wounds that are prone to infection. There are no other known medical contraindications other than the physical limitations of the patient.

Warnings

To ensure accurate patient testing, you must replace the Brentwood accessories used with this device with accessories manufactured by Brentwood Medical Technology Corp.

The American Thoracic Society (ATS) Standardization of Spirometry, recommends the use of rubber gloves when replacing Disposable Pneumotach Mouthpieces (DPM), and hand washing after touching DPMs.

Precautions

Read and observe the following precautions to ensure the proper operation of this device.

1. Familiarize yourself thoroughly with the operational procedures of the device prior to use. It is recommended that the user be trained in the methods of administering spirometry tests to a patient by an organization that is certified by a recognized agency.
2. Installation location and maintenance of the device.
 - a) Avoid installing the device in direct sunlight. Install and keep the device away from splashing fluids.
 - b) Do not install the device where it may be affected by significant or extreme changes in humidity, ventilation, air borne particles containing dust, salt, sulfur, etc.
3. Prepare the device for operation according to instructions in this operation manual.
4. Precaution while using device - Observe the patient closely. If any abnormality is observed, proper action, which may include stopping the test, should be taken immediately.
5. Precaution after using device - The software turns off the device power according to programmed procedures. Keep the device clean at all times to ensure trouble-free operation.
6. In case of a malfunction, call Technical Support and precisely describe the problem.
7. Perform routine inspection on the device. Keep all items in a clean environment.
8. Do not make any modifications to the device; any modifications made will void the warranty.
9. Do not open the device handle. Refer servicing to qualified service personnel.

Adverse Reactions

The IQmark Digital Spirometer is a non-invasive device and is safe in both construction and use. This has been confirmed by the performance of Verification and Validation Testing, Biocompatibility Testing, Risk Assessment Analysis, and ATS testing.

The following minor complications can occur with all diagnostic spirometers:

1. Infection or injury due to the use of a non-sterile mouthpiece over open wounds
2. Skin or mucous membrane abrasion caused by prolonged rubbing or excessive use of the mouthpiece (not related to biocompatibility issues)
3. Nasal, oral, or dental pain
4. Drying of oral or pharyngeal mucosa
5. Congestion or irritation of Eustachian tubes
6. Gastric distention or flatulence from ingested air
7. Slight discomfort during test procedures
8. Decreased secretion clearance during test procedures
9. Aspiration of secretions
10. Hyperventilation and possible dizziness

Patients may become light-headed, dizzy, or even faint during a test maneuver. Be sure to watch the patient closely and place a chair behind the patient before beginning any procedure.

Electrical, Safety, Biocompatibility Standards

This Spirometer has been tested to comply with the following standards:

UL STD 2601-1

CAN/CSA STD C22.2 601.1-M90

IEC 601-1 (Electrical)

IEC 60601-1-1 (Safety)

EN 60601-1-2 (EMC)

ISO 10993-5 (Cytotoxicity)

ISO 10993-10 (Irritation and Sensitization)

I. General Information

A. Description

The IQmark Digital Spirometer is a portable device that converts a Microsoft Windows-based personal computer (PC), be it desktop, laptop, notebook, or pen-based, to a fully functional diagnostic spirometer with interpretive capability. The device is electronically isolated from the PC and connects to it through the serial port.

Together with the Diagnostic Workstation, the Spirometer makes it easy to record spirometry efforts, interpret them, and archive them for future reference.

B. Necessary Computer Skills

This manual assumes that you are already capable of using Windows based applications, that you have some understanding of how a PC works, and that you are familiar with the basic operations of Windows. If this is true, you will have no problem using the product. However, in the event that you have any technical questions or problems, please refer to the Troubleshooting Guide in Appendix C of this manual for immediate troubleshooting assistance. Customer Support contact information is also listed in Appendix R.

C. Configuration

Block Diagram

The block diagram below illustrates the configuration of the system. The primary components are a Windows-based PC, a printer, and the IQmark Digital Spirometer handle. A portable computer is recommended if mobility is a consideration.

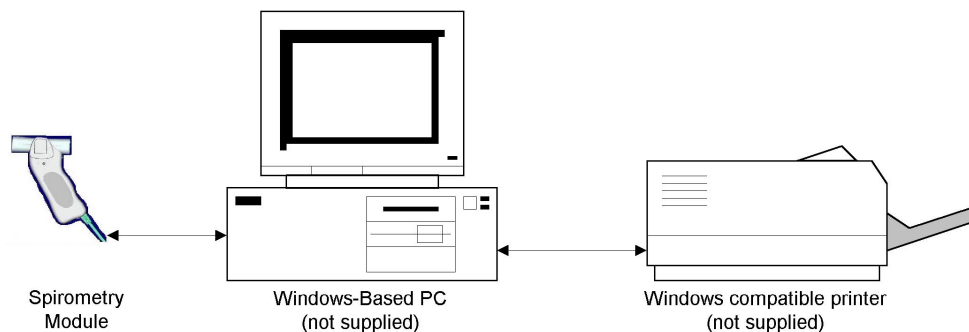


Figure 1.0 **Block Diagram for the IQmark Digital Spirometry system**

D. System Specifications

The following are the physical and performance specifications for the device.

Spirometer Specifications

Performance Specifications	
Category	Specification
Intended Use	To provide diagnostic spirometry results that a licensed practitioner can use to interpret the current condition of a patient's lungs.
Physical Characteristics (Handle)	- Approximately 7" (178mm) x 2 1/4" (57mm) x 1.5" (38mm) (HxWxD) 10 oz. (Handle w/batteries) - Two 1.5V AAA alkaline batteries - Cable that plugs into a standard serial port (DB9 or DB25 with an adapter)
Anatomical Sites	Non-invasive device
Patient Contact	Disposable Pneumotach Mouthpiece (DPM)
Safety Parameters	Battery operated – no power drawn from or delivered to the computer.
Spirometry Acquisition	- Fleisch Pneumotach – differential pressure reading of flow with a DPM - Volume determined by flow integration
Ranges	+/- 14 L/s – Flow +/- 8 L – Volume 30 s – Maximum Measuring Time
Environmental Conditions (temperature and humidity)	15°C to 40°C 10% to 90% Humidity, non-condensing
BTPS	Automatic BTPS Correction
Analysis & Measurement	- Automatic Back Extrapolation calculation - Automatic spirometry parameter calculation - Automatic comparison to published Spirometry Predicted Equations (Reference Values) - Automatic interpretation of test results
Parameters Measured	See Appendix L
Reference Values Sets	See Appendix H & I
Interpretations	- ATS (1991) - Appendix F - NHANES III (NLHEP 1999) - Appendix G
Printer	Windows supported ink jet or laser printers
Paper	8.5" x 11" (Letter size) or 210mm x 297mm (A4 size)

II. System Installation

A. Hardware and Software Requirements

Both the Diagnostic Workstation and the IQmark Digital Spirometer are 32-bit Windows-based software. The software will occupy 10 megabytes (MB) of disk space. Additional disk space is required if you choose to store the results of the spirometry tests performed. Storing the data is optional. This software shall run on a personal computer using a Pentium 100 MHz or faster processor, running Windows 95, Windows 98, Windows NT 4.0, Windows Me, Windows 2000, or Windows XP. For each operating system listed, the spirometry program will run on the minimum RAM requirements as recommended by Microsoft:

Windows 95/98/Me	16 MB of RAM
Windows NT	32 MB of RAM
Windows 2000, XP	64 MB of RAM

In order to install and successfully use the Spirometer, your computer must meet the following minimum requirements:

1. IBM compatible PC with Windows 95/98/Me, Windows NT, Windows 2000 or Windows XP. *Precaution: The Workstation and Spirometer have been tested for proper function with the Off-The-Shelf (OTS) Operating Systems (OS) specified in this manual. Do not operate the Workstation and Spirometer with an operating system other than the OTS OS specified. Future releases of currently approved operating systems should not be used until Brentwood has had an opportunity to test the Spirometer with them. Before updating your operating system, contact Brentwood for the latest OTS OS information.*
2. Keyboard, mouse, and a CD-ROM drive.
3. VGA display accommodating 640x480, 800x600, 1024x768, 1280x1024, or higher resolution. Minimum 256 colors (16-bit color recommended).
4. One (1) serial port (RS232C port, usually COM1 or COM2) or a USB port using a USB to Serial Port adapter.

B. Hardware Installation

1. Remove the items from its packaging and verify that you have the following:
 - IQmark Digital Spirometry software installation CD (Diagnostic Workstation software is included on CD)
 - IQmark Digital Spirometer Handle with built in serial cable
 - 10 Single Patient Use, Disposable Pneumotach Mouthpieces and nose clips
 - Four (4) AAA alkaline batteries

2. Hold the handle upside down (so that the cable is aiming upward); push the battery compartment cover from the middle of the device towards the edge until the cover slides approximately $\frac{1}{4}$ of an inch. Remove your finger from the cover, the cover will pop upward when released. Insert two (2) AAA batteries into the battery holder, negative side in first making sure to follow the battery polarity diagram (negative side towards the top) located on the lower side of the handle. Close the battery compartment cover.
3. Attach the female end of the 9-pin communication cable to an available PC serial port. You may also use a 9-pin-to-25-pin adapter as necessary (see note below). Secure the connections with the thumbscrews. Do not over-tighten.

Note: If using a 25-pin serial port (e.g., COM 2), connect the 25-pin (female) -to- 9-pin (male) adapter to the port on back of the computer. Then connect the female end of the 9-pin connector on the communication cable to the 9-pin port on the adapter.

 **NOTE:** **For Brentwood Windows Holter and ECG users only.** If you have already installed one of these Brentwood Programs and its security key in the same PC, you will not need to adjust the security key. If you are upgrading your Holter software, you will need a new security key.

C. Software Installation

Before installing the IQmark Digital Spirometry software on your computer, it is important that you understand and carry out the following tasks appropriately.

Windows Taskbar

The Diagnostic Workstation is designed to run as a full screen program. For best results, the Windows Taskbar should be set to Auto hide to provide maximum display area. To do so, position the mouse pointer on the gray portion of the Taskbar on bottom of the screen. Press on the right mouse button and select **Properties**. Make sure the Auto hide box is checked. Click OK.

Screen Saver

If screen saver or any energy saving feature is enabled on the computer, disable it. Refer to your computer or software manual to find and change these settings.

Updating from Brentwood Diagnostic Workstation versions 2.x software and older

If you are updating from a version of Brentwood Diagnostic Workstation earlier than version 3.0 and have ECG or Holter records that you would like to retain and transfer to the new version, you must first archive those records. Then you must uninstall the old Diagnostic Workstation version, install this new version and restore the archived records. Refer to the Diagnostic Workstation Operation Manual for instructions on updating.

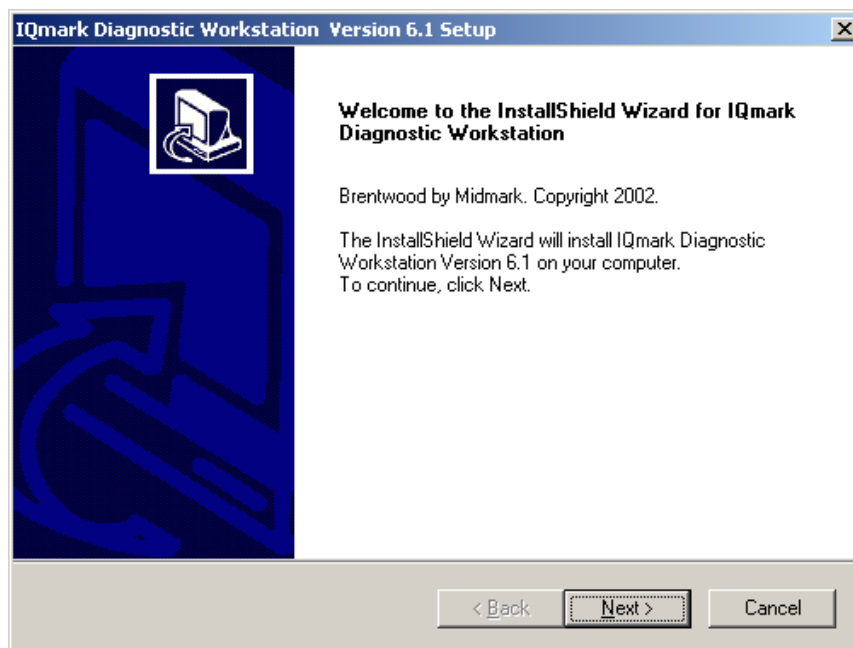
IQmark Digital Spirometer Operation Manual

If you do not have any patient records that you would like to retain and transfer to this new version, you can simply uninstall your version of Diagnostic Workstation and install this new one. Refer to the Diagnostic Workstation Operation Manual for instructions to uninstall older versions.

Installing the IQmark Digital Spirometer (and Diagnostic Workstation)

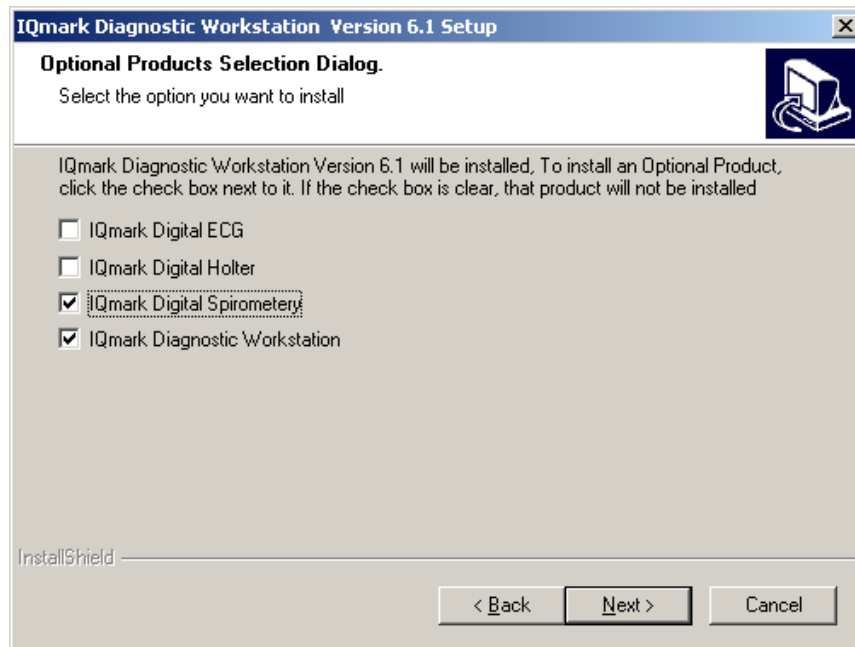
NOTE: Close all Windows programs before running this software installation. Once the installation program is initiated, it should not be interrupted until completed. The approximate installation time is five minutes.

1. Insert the Brentwood software CD into the CD-ROM drive.
2. The CD automatically starts the installation. Follow the instructions on the screen. Click **Next** to continue. Then read the **license agreement** and select the appropriate choice. You must select **Yes** to proceed with the installation. If you accept the license agreement, proceed to step 3.



IQmark Installation – Opening Screen

3. Now select the software for the hardware you have purchased. The Workstation selection is highlighted. If you have purchased only the Spirometer, use the mouse to select IQmark Digital Spirometer and click on **Next** to continue. If you have purchased more than one modality, please select all that apply.



Select the software application for your hardware

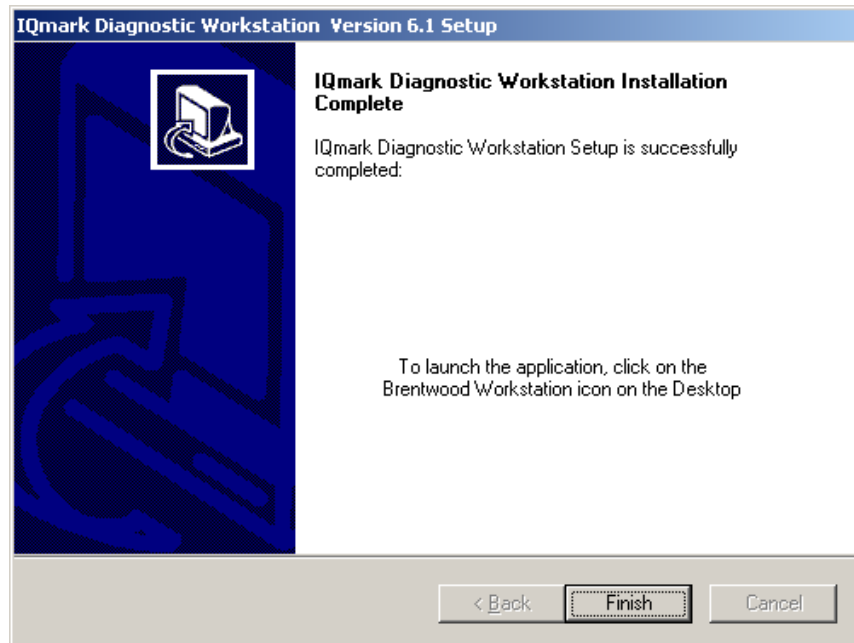
The program will automatically select the Brentwood directory to install the software. Select **Next** to install. When finished, the installation software displays the registration page. Please enter your appropriate information and click the **Print** button. This will print a registration page that you can fax to Brentwood.

Institution Name	Brentwood Medical Technology
Institution Address	3300 Fujita Street Torrance, CA 90505
Contact Name	Brent Harrison Wood
Institution Telephone	310-530-5955
Institution Fax	310-530-1421

PRODUCT INFORMATION	
	Serial Numbers
Digital ECG	03823
Digital Spirometry	03323
Holter Security key	4040-6845
Digital Holter Recorder(s)	370658; 370481 370845

Registration Page

If you do not have Adobe Acrobat Reader Version 5.0 installed on your computer, the installation software will ask you to install it from our installation disk. You must install this Reader to view and print our on-line Operation Manuals. Please select the appropriate buttons to install the Reader.



Successful Installation Screen

Click the Finish button to end the installation.

You can access the online Operation Manual from the Windows Task Bar through the following sequence:

Start → Programs → Brentwood Workstation → Spirometry Manual

4. The installation program adds at least three shortcuts to your Windows desktop: one for the **IQmark Workstation**; one for the **IQmark Configuration**; one for the **Spirometry Calibration**. You can use the **IQmark Configuration** or the **Spirometry Calibration** program to set the communications port that the Spirometer uses or to set up your network database. If you installed the Adobe Reader, this icon is also added to your Windows desktop.

NOTES:

1. The diagnostic spirometer application uses the **IQmark Diagnostic Workstation** to manage patient records. When you install or upgrade the Spirometer, the IQmark Diagnostic Workstation is automatically installed or upgraded accordingly.

2. You may also access other Brentwood PC-based products, such as the Holter or ECG, from the **IQmark Diagnostic Workstation**, if the product is installed on the same computer. Call Brentwood for the latest information on additional PC-based diagnostic products.
3. The **IQmark Diagnostic Workstation** is called the Diagnostic Workstation for the remainder of this manual.

D. Configuring The Spirometer

The Diagnostic Workstation can be configured to meet your individual needs. Along with the application program, a configuration program has been installed that enables you to individualize the Spirometer for your operation.

Access the configuration program from the Windows Task Bar through the following sequence:

Start → Programs → Brentwood Workstation → IQmark Configuration

or

Double click the **IQmark Configuration** icon to start the configuration application.



The following dialog box will appear.

 A screenshot of the 'Brentwood Workstation Configuration Settings' dialog box. The dialog has a title bar with a close button. It contains several input fields and groups of radio buttons. The 'Institution Name' field is set to 'Brentwood by Midmark'. The 'Institution Address' field is set to '3300 Fujita Street, Torrance, California 90505'. There are three groups of radio buttons: 'Units' with 'English' selected, 'Date Format' with 'MM/DD/YY' selected, and 'Time Format' with '24 Hour Clock' selected. There are also buttons for 'Serial Port', 'Database Settings', 'List Management', 'Line Frequency' (with '60 Hz.' selected), and 'Default Fax Printer' (with a 'Select' button). At the bottom are 'OK', 'Cancel', 'Default', and 'Help' buttons.

Configuration Settings Dialog Box With Default Values

The spirometry settings in the **IQmark Configuration** program are also available and can be changed from the **Spirometry Calibration** icon, the **New Test** screen and the **Calibration** screen, with the exception of the Date and Time format. To access the spirometry settings, please see Setup Configuration Items in this section.

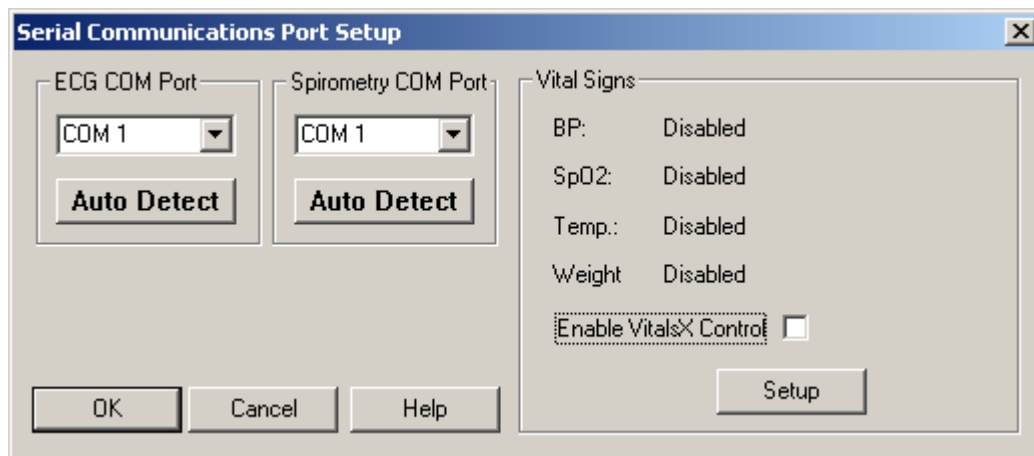
Once you are satisfied that the configuration selections are set appropriately, click **OK** to save the settings. These settings are applied the next time the Diagnostic Workstation is started or immediately if you make the changes from the **New Test** screen. If you decide not to make changes to the configuration, simply click **Cancel** and no changes are made. You can also click the **Default** button to restore all settings to the default values except for **Institution Name** and **Address**.

Enter the **Institution Name** and **Address** fields of your own medical practice. The software will display the **Institution Name** on printed reports. Enter a name that describes your practice or operation to enable other medical personnel to recognize the origin of your reports.

In the configuration screen, you can choose International (Metric) and American (English) units of time and measurement, and an AC power source frequency of 50 Hz or 60 Hz. The frequency setting is necessary for the ECG module (if you have added it to your computer). Refer to the ECG manual for information on frequency.

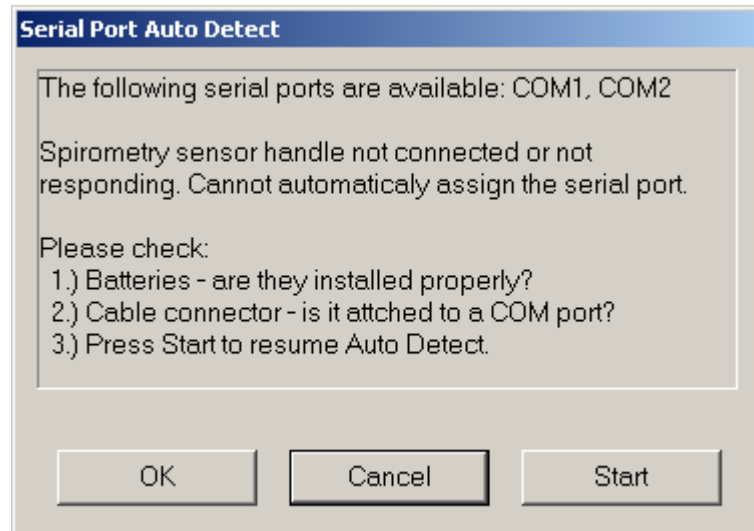
The configuration screen also enables you to select the **Serial Port** being used by the Spirometry Module. Click the **Serial Port** button to open the following dialog box.

NOTE: The default **Communications Port** is **COM 1**. If you have connected the Spirometry Module to COM 1 on the computer, as is the case for most Laptop or Notebook users, you will not need to change the port setting through the **IQmark Configuration** program. If COM1 is not available, the software can **Auto Detect** the Spirometer. See below.



Serial Communications Port Setup

Click the **Auto Detect** button to find the port that the Spirometry Module is connected to. To use the **Auto Detect**, you must have the Spirometry Module connected to an available serial port on the computer. Click the **Auto Detect** button on the right. If **Auto Detect** cannot find the Spirometer, the following screen will appear:



Auto Detect Screen

Check the items listed and click **OK**. When the software finds the Spirometry handle, click **OK** to select the correct port.

Click the **Database Settings** button in the configuration screen to switch between your local database and the network database (if enabled).

The **List Management** button enables you to add, edit, or delete items in the various lists used in the Diagnostic Workstation. The **Default Fax Printer** enables you to assign an electronic fax if you have one installed on your computer. Refer to the Diagnostic Workstation Operation Manual for more information on these features.

Setup Configuration Items

You can select additional setup items specific to the Spirometer from the Spirometry Settings dialog box. To open this box, click on the **Settings** button. The **Settings** button can be found when opening the **Spirometry Calibration** icon or in the **New Test** screen or the spirometry **Review and Edit** screen within the Workstation program. Clicking the **Settings** button will display the following configuration menu.

Spirometry Settings – Configuration Tab

NOTE: The original configuration profile is set to Default. The Default profile *cannot* be changed. You must click the **Add New** button to create a new profile to change the spirometry settings. Once a new profile is added, you can change the settings on the other tabs. Other preset profiles are shipped with the instrument. Any of the other profiles can be modified or deleted.

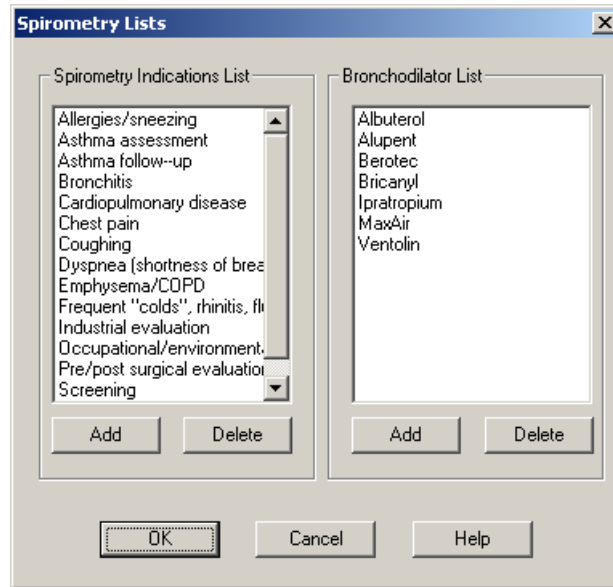
Configuration Tab

Click the **Add New** button in the Configuration Profile area of this tab. Assign a name, e.g. Default 2, and click **OK**. You can now modify the selections in the setup menu. Changing the **Institution Name** and **Institution Address** will change the header of your reports. Both fields are optional.

The **Manage Lists** button enables you to modify the **Indications List** and the **Bronchodilator List**. You can add or delete items from either list.

To add to a list, simply click the **Add** button under the appropriate list and type a new item.

To delete an item from a list, highlight the item you wish to delete and click the **Delete** button.



Managed Lists Dialog Box

For example, if a doctor uses only Albuterol for a bronchodilator, this list can be modified so that Albuterol is the only selection available. The list always appears in alphabetical order.

Reports Tab

From this tab, you can select which reports to print whenever **Print** is selected. For example, the **Reports Tab** shown has three additional report boxes selected (Best 3 Pre-BD FVC; Pre and Post BD FVC; Pre and Post BD MVV). For each additional check box selected in any one of the **Reports** areas, the printed the report will include an additional page.

In the example below, the **Cover Page** box is selected, three additional report boxes are selected and the Calibration Report box is selected. If a test session only contains Pre-BD FVC tests, clicking on **Print** will print a four page report. The first page is the Cover Page, the second page is the Best 3 Pre-BD FVC tests performed, the third page is the best Pre-BD test and the fourth page is the Calibration report.

If the **Cover Page** box is the only box selected, only a one-page report will print because no additional **Reports** boxes are selected.

Spirometry Settings

Interpretation | Measurements | Calibration
 Incentive/Miscellaneous | Trending | Ethnic Adjustments
 Configuration | **Reports** | Cover Page Settings

☒ **Cover Page**

FVC Graphic Reports

- ☐ All Pre-BD FVC
- ☒ Best 3 Pre-BD FVC
- ☐ All Post BD FVC
- ☒ Best 3 Post BD FVC
- ☐ Pre and Post BD FVC

MVV Graphic Reports

- ☐ Best 3 Pre-BD MVV
- ☐ Best 3 Post BD MVV
- ☒ Pre And Post BD MVV

VC Graphic Reports

- ☐ Best 3 Pre-BD VC
- ☐ Best 3 Post BD VC
- ☐ Pre And Post BD VC

☒ Vol/Time Predicted Curve
☒ Flow/Vol Predicted Curve
☒ Print Test Quality Statements
☒ Use ATS Graph Scales
☐ Print Using Color

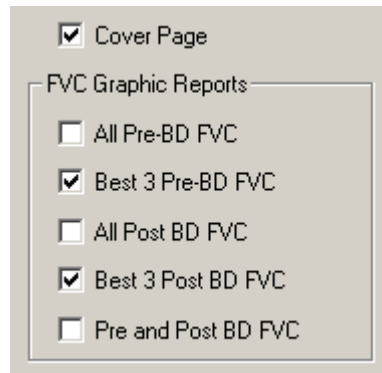
☐ Print Calibration Report

Help

OK Cancel Apply

Spirometry Settings – Reports Tab

If the patient has both Pre- and Post-Bronchodilator tests saved, all applicable selected reports will print when the **Print** button is clicked.



The screenshot shows a settings window with a 'Cover Page' checkbox checked. Below it is a section titled 'FVC Graphic Reports' containing five checkboxes: 'All Pre-BD FVC' (unchecked), 'Best 3 Pre-BD FVC' (checked), 'All Post BD FVC' (unchecked), 'Best 3 Post BD FVC' (checked), and 'Pre and Post BD FVC' (unchecked).

Cover Page, Best 3 Pre and Best 3 Post Selected

Another feature of this tab enables you to select the **Calibration Report**. If this option is selected, every time you print a patient's report, the calibration that was performed prior to that test is printed with the report. This is especially helpful if proof of calibration is required.

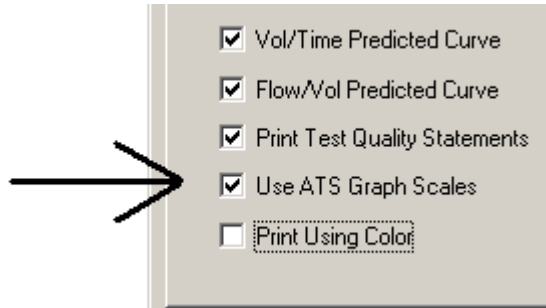
There are five selections at the bottom left of this tab. Four of these selections – **Vol/Time Predicted Curve**, **Flow/Vol Predicted Curve**, **Use ATS Graph Scales**, **Print Using Color**, affect all reports, including the cover page. **Print Test Quality Statements** only affect the reports selected in the **Report** areas – they do not affect the cover page.

For example, if the **Predicted Curve** boxes are selected, the predicted Volume/Time and predicted Flow/Volume graphs for the patient are printed on the secondary report pages and will also print on the cover page graphs.

The **Cover Page Settings** tab has separate selections for **Smoking History**, **COPD Risk**, **Lung Age** and **Test Quality Statements**. Please see the next section for additional information about the **Cover Page Settings** tab.

ATS Recommended Graph Size

The ATS recommends that a Volume Time graph be at least 20 mm per second and 10 mm per liter when hand measurements are required. Some government agencies and insurance carriers require this for reimbursement. All cover page graphs will not print to this scale size but all reports from the Reports tab will if Use ATS Graph Scales is selected. Please use this setting if requested from your carrier.



Enable ATS Graph Scales

Cover Page Settings Tab

This tab enables you to customize your cover page. Selections on this tab only change the look of the cover page: they do not affect additional report pages. The first selection determines whether the volume-time and flow-volume graphs are printed on this page.

The Pre and Post BD Table Format selections determine whether the report includes only the Best Pre and Best Post BD test or the Best 3 Pre and Best 3 Post BD tests. This option is available when both Pre and Post BD tests have been saved.

If the patient has performed only Pre or Post BD tests, the Pre Or Post BD Table Format selections will take effect.

The check box selections at the bottom of this page determine what additional information appears in the patient demographics field of the cover page. These selections do not affect any of the additional report pages.

The screenshot shows the 'Spirometry Settings' dialog box with the 'Cover Page Settings' tab selected. The dialog has a title bar with a close button. Below the title bar are several tabs: Interpretation, Measurements, Calibration, Incentive/Miscellaneous, Trending, Ethnic Adjustments, Configuration, Reports, and Cover Page Settings. The 'Cover Page Settings' tab is active, showing the following options:

- ☒ Table And Graphs (Single Page Report)
- ☐ Table Only
- Pre And Post BD Table Format:
 - ☒ Best Pre And Post BD
 - ☐ Best 3 Pre And 3 Post BD
- Pre Or Post BD Table Format:
 - ☐ Best Pre Or Post BD
 - ☒ Best 3 Pre or Post BD
- ☒ Print Smoking History
- ☒ Print COPD Risk
- ☒ Print Lung Age
- ☒ Print Test Quality Statements

At the bottom right of the dialog is a 'Help' button. At the very bottom are 'OK', 'Cancel', and 'Apply' buttons.

Spirometry Settings – Cover Page Settings Tab

Interpretation Tab

From this tab, you can select which Reference Equations set to use as the default for Adults and Pediatrics. Not every spirometry measurement (FVC, FEV₁, etc) are calculated by every Reference Equation. The Secondary reference equations can be used to “fill in” missing measurements. For example, if your primary reference equation does not have an equation for FEF₂₅, you can select a secondary reference equation that does to “fill in” your report.

Spirometry Settings – Interpretation Tab

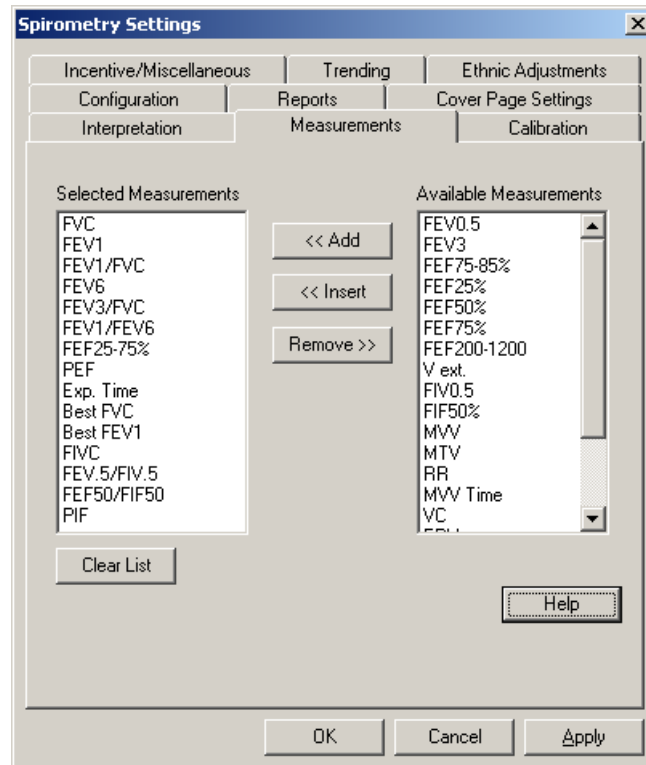
You can also turn on or off the Automatic Interpretation feature. If the Auto Interpretation box is selected, you may select between the ATS Logic and the NHANES III logic. If you do not wish to have the software automatically interpret the spirometry tests, clear the Auto Interpretation box.

The third area on this tab, FVC Settings, enables you to define the acceptable *length of test* required. Reducing this number will affect the *length of test* acceptability error code. The ATS recommends that the minimum *length of test* be set to 6 seconds.

Measurements Tab

This tab enables you to customize which measurements appear on the cover page, the test screen and the review screen. You can customize these settings to show only the measurements you desire. You must select at least one measurement.

If you have selected the **Tables and Graphs** setting for your **Cover Page**, the cover page report displays only the first 9 measurements selected. If **Table Only** is selected, the cover page displays up to 28 measurements.



Spirometry Settings – Measurement Tab

You can place the measurements in any order you wish by using the **Add**, **Insert**, and **Remove** buttons. Highlight the measurement with your mouse and then choose the desired function.

- Choose the **Add** button to place the newly selected Available Measurements at the bottom of the Selected Measurements list.
- Choose the **Insert** button to place the newly selected Available Measurements above the currently highlighted item in the Selected Measurements list.
- Choose the **Delete** button to remove an item from the Selected Measurements list. To use the **Delete** button, highlight a measurement from the Selected Measurements list and click the **Delete** button. The measurement will return to the Available Measurements list.

Ethnic Adjustments Tab

This tab enables you to customize the percentages that the predicted value equations are adjusted when testing a specific ethnic code. These percentages can only be adjusted if the **Use Default Settings** box is not selected, as show below. When this box is selected, the program will set the percentages as stated in the Adjustments to Reference Values Equations set in the Appendix.

It is recommended that you use the default setting for testing.

The screenshot shows the 'Spirometry Settings' dialog box with the 'Ethnic Adjustments' tab selected. The 'Use Default Settings' checkbox is unchecked. The dialog is divided into two columns: 'Adult Settings' and 'Pediatric Settings'. Each column contains a list of ethnic groups with corresponding percentage values in input boxes. The 'Adult Settings' column has values: 85% for African - American, 85% for African - European, 100% for American Indian, 85% for Asian, 85% for Black, 100% for Caucasian, 100% for Hispanic, and 100% for Other. The 'Pediatric Settings' column has values: 88% for African - American, 88% for African - European, 100% for American Indian, 85% for Asian, 88% for Black, 100% for Caucasian, 100% for Hispanic, and 100% for Other. At the bottom of the dialog are buttons for 'OK', 'Cancel', 'Apply', and a 'Help' button.

Group	Adult Settings (%)	Pediatric Settings (%)
African - American	85	88
African - European	85	88
American Indian	100	100
Asian	85	85
Black	85	88
Caucasian	100	100
Hispanic	100	100
Other	100	100

Spirometry Settings – Ethnic Adjustments Tab

E. Calibration

The ATS recommends daily calibration of any Spirometer. The IQmark Digital Spirometer automates this process for quick and accurate preparation of the instrument.

Calibrating the Spirometer requires a 3-Liter syringe. Brentwood strongly recommends a Brentwood 3-Liter syringe with the Brentwood Calibration Adapter.

NOTE: The Spirometer handle must be calibrated with a Disposable Pneumotach Mouthpiece (DPM). The DPM must be calibrated with a Calibration Adapter that fits OVER the outside diameter of the mouthpiece. The user must never calibrate the device with a syringe that fits within the DPM.

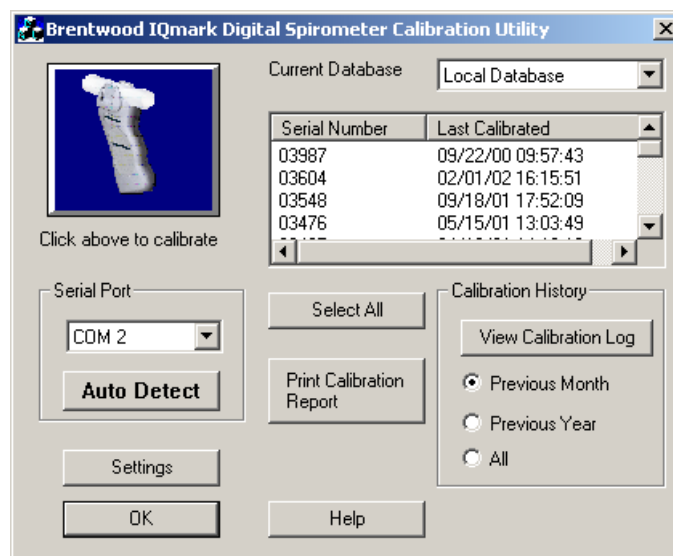
You can access the Calibration program from the Windows Task Bar through the following sequence:

Start → Programs → Diagnostic Workstation → Spirometry Calibration

or Double click the **Spirometry Calibration** icon:



The following screen is displayed. Click the handle icon in the upper left corner to Start Calibration. Clicking OK will close this screen and return to the desktop.



Spirometry Calibration Utility Screen

IQmark Digital Spirometer Operation Manual

Clicking on the handle will display the following calibration screen.

Spirometry Calibration					
Date	06/10/02 15:21:51	Sensor ID	1491834873	Previous Calibration	
Performed By	GM	Sensor SN	03314	Date	06/10/02
Syringe Volume	3000 ml.	Temperature	76 deg. F	Pressure	759 mmHg
Syringe S/N	02-008349	Accepted Pumps	3	Temperature	76 deg. F
Pressure	759 mmHg	Avg. Volume	2.91 liters	Avg. Volume	2.94 liters
Corr. % Change	-2.1	Correction	1.03	Correction	1.02

Calibration Volume vs. Time

Sensor: Ready

Volume in liters

Time in seconds

To begin calibration, click on New. Enter the data for Performed By, Syringe Volume, Syringe S/N, Pressure and Sensor SN. Then press Start to begin calibrating.

Print	Verify	New Cal	Start Cal	Settings	Help	Exit

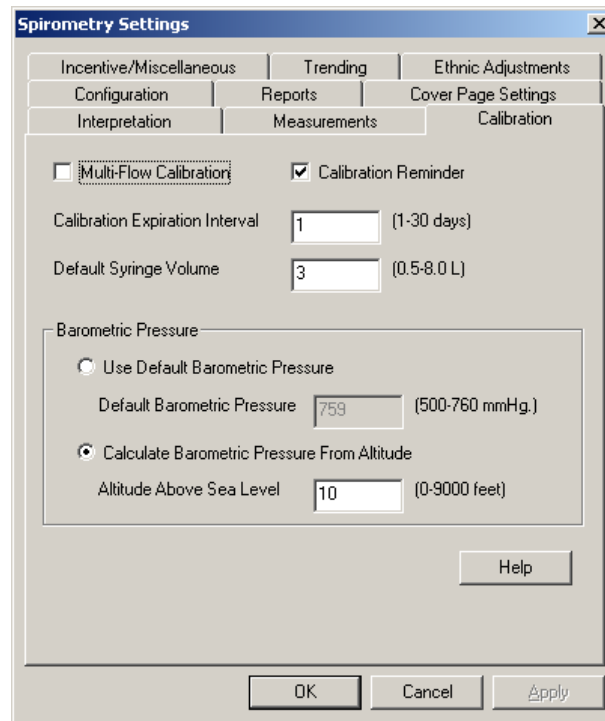
Calibration Screen

Barometric Pressure

The Pressure must be set prior to the first time you calibrate the system. It only has to be changed if you change the location of the instrument and the altitude changes. Click the **Settings** button to open Spirometry Settings. Select the **Calibration** tab and enter the Barometric Pressure in the Default Barometric Pressure box. If you do not know the barometric pressure, you can select Calculate Barometric Pressure From Altitude and enter your altitude. The software will automatically calculate and store the usual barometric pressure for that altitude.

NOTE:

The proper Barometric Pressure or altitude **MUST** be entered to assure a proper calibration.



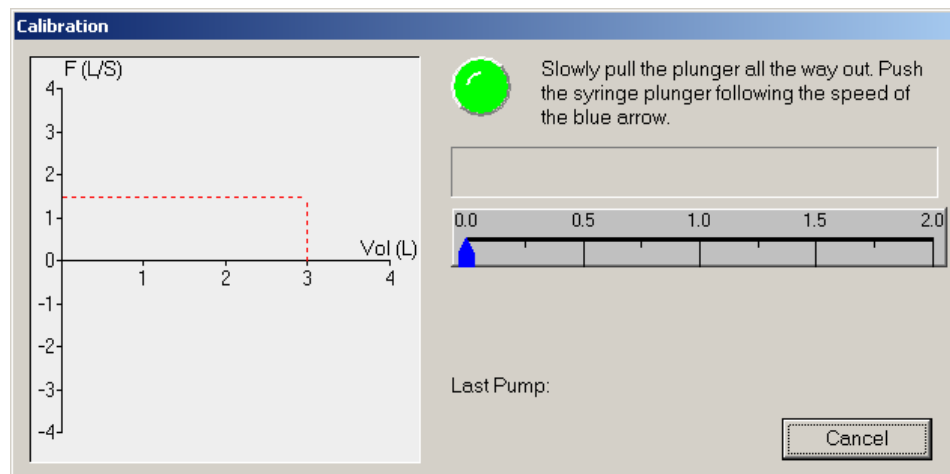
Spirometry Settings – Calibration Tab

Select the Calibration Reminder box to remind the user when the Spirometer has not been calibrated for the interval set in the Calibration Expiration Interval box.

Starting a New Calibration

Click New Cal to begin a new calibration. Attach the 3-liter syringe to the Calibration Adapter, then attach the mouthpiece to the adapter and attach the mouthpiece to the handle. The first time you calibrate your spirometry handle, you must type your name in the Performed by box, the Syringe serial number and spirometer handle serial number in the appropriate boxes.

Click Start Cal. The sensor will zero itself and then the following screen appears.



Calibration Pump Window

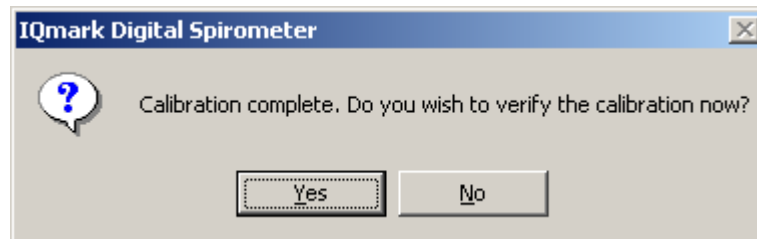
Follow the instructions displayed. Use the red dotted line and/or the blue timer arrow as a target flow rate. Try to inject the air from the syringe at a rate close to that of the red line.

Remember that the syringe handle attached to the plunger must be pulled all the way out before you inject. Once the handle is all the way out, inject the air from the syringe until the handle is all the way in. **PUSH THE HANDLE IN AND DRAW THE HANDLE OUT SMOOTHLY – TRY NOT TO “BANG” THE PLUNGER AS YOU PERFORM THE MANEUVER.** “Banging” the plunger can cause the timer arrow to start to count. If it does, just wait for the timer to reset and inject the plunger. This will not affect the calibration results.

If the pump is performed correctly, the program will prompt you to begin a second injection. Repeat the process, injecting all of the air in the syringe.

If the injection is not performed correctly, the system will discard the attempt and prompt you to inject again.

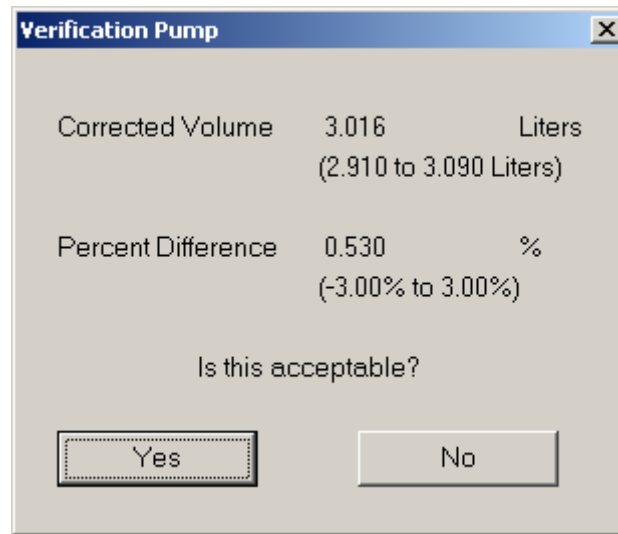
After three correctly performed injections, the system will automatically calculate a correction factor and prompt you to verify the calibration. **ALWAYS VERIFY YOUR CALIBRATION.** After a verification injection, the software will display the measured volume and the percentage difference from 3.0 Liters. The ATS recommends that the verified volume should be between 2.91 and 3.09 (+/- 3.0 %) to be accepted. Be sure to check these numbers before accepting the verification.



Calibration Complete Window

The verification acceptance window will display those numbers for quick and easy comparison. Click **Yes** if the verification flow is within the recommended parameters. If the flow is not within the parameters, click **No** and repeat the verification flow.

After you accept the verification, the system automatically saves the calibration. To print the calibration report, click **Print** and select **PRINT** from the menu. To view the calibration report, click **Print** and select **PRINT PREVIEW** from the menu.



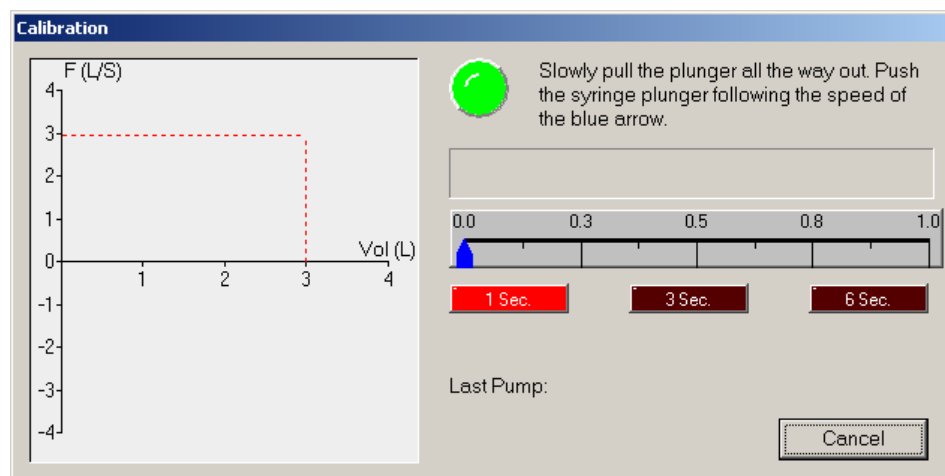
Verification Acceptance Window

After you have printed or reviewed the calibration report, click **Exit** to start testing.

Social Security Disability – 3 Flow Calibration

SSD and OSHA require a calibration at three different flow rates. Brentwood has incorporated a feature that requires you to calibrate at 0.5 L/s, 1.5 L/s and 3.0 L/s.

On the **Calibration Tab** of Spirometry Settings, there is a check box for Multi-Flow Calibration. If this box is selected, you must calibrate at three different flow rates. The program will display the Multi-Flow Calibration window and will measure the flow rates as the user injects the 3 liters. If the flow is too fast, the program will reject the injection and ask the user to try again with a slower injection. If the flow is too slow, the program will reject the injection and ask the user to try again with a faster injection.



Multi-Flow Calibration Window

III. Operation

NOTICE

This Spirometer has been designed and tested to meet the appropriate sections of IEC 60601-1-1, IEC 601-1, IEC 60601-1-2, UL 2601-1 and ETL (CSA and UL).

A. Introductory Notes

This manual describes how to use the various features and the operational sequence most users will follow when operating the IQmark Digital Spirometer. However, you are not restricted to follow in this particular sequence. The bottom or right side of each screen has a menu bar that lists other screens that may be accessed. To visit any of these screens, simply click the appropriate button.

Of course, certain sequences must always be followed, such as entering a patient's demographics and medical data prior to performing a spirometry test. For your convenience, a condensed guide to the operation of the Spirometer with new patients is listed in the Appendix under section B, *Spirometry Testing at a Glance*. Use this guide until you become more familiar with the use and operation of the program. Appendix O, P, and Q can be used for more advanced users and for Pre/Post testing.

Pulmonary Function Test or PFT is another term widely used for spirometry. You may hear people refer to this device as a PFT machine. Technically, a spirometer is a device used by a patient to perform a PFT. In this manual, the words spirometer or spirometry are used when referring to the Brentwood device and its operation.

Prescription Device

“Caution: Federal law restricts this device to sale by or on the order of a medical practitioner licensed by the law of the state in which that person practices.”

B. Patient Preparation

NOTE: The ATS recommends daily calibration of spirometers using a 3-liter syringe. See Calibration in the Installation section for instructions.

Each patient must be prepared for the Spirometer test procedure. It is essential that you comply with the following instructions on patient preparation as closely as possible. Otherwise, the integrity of the spirometry data may be compromised.

Show every patient the proper way to perform a test. It is recommended that the user perform at least one forced expiratory maneuver to demonstrate the procedure to the patient. This test does not have to be performed on this Spirometer but it should be

performed using a mouthpiece. Remember that spirometry depends on patient effort – the coaching and enthusiasm displayed towards the patient should emphasize the importance of good performance during the test.

C. Starting The Program

The application that you will use to start the Spirometer is called the **IQmark Diagnostic Workstation** and is located on your Windows desktop as a shortcut icon. Double click on this icon to start the Diagnostic Workstation program.

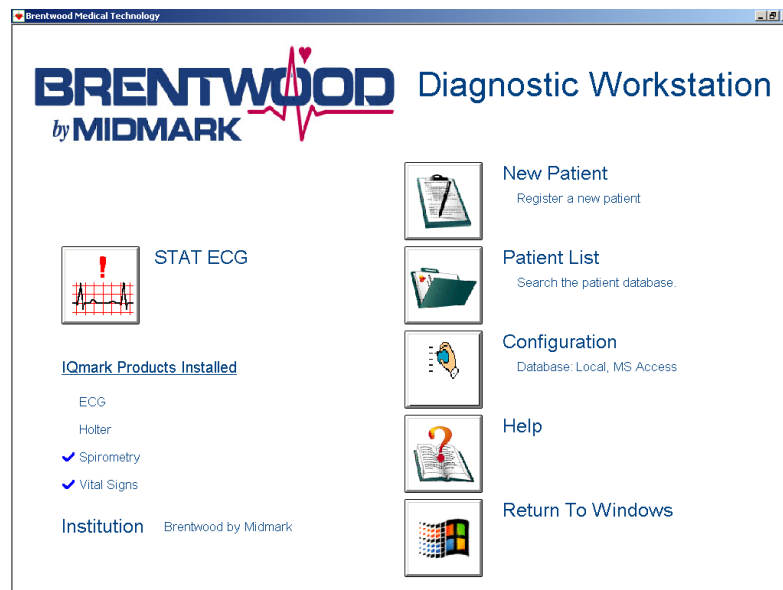


OR Starting from the Windows Task Bar, go through the following sequence:

Start → Programs → Brentwood Workstation → Workstation

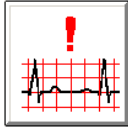
D. Opening Screen

When you start the Diagnostic Workstation application, an opening screen appears. The IQmark Products Installed will have a check mark to the left if a product is installed on your computer. Call Brentwood Sales for information about available add-on products.



Opening Screen

There are six choices on the opening screen:



STAT ECG – Please see the IQmark Digital ECG Operation Manual for information on this feature. It is not part of the IQmark Digital Spirometer program.



New Patient – Enables you to register and proceed with spirometry or other installed medical testing for a new patient.



Patient List – Enables you to view a list of patients previously tested or previously entered into the database. Selecting a patient from the list enables you to access that patient's records and data from previous tests.



Configuration – Displays what database is currently selected and enables the user to configure the program to meet their needs. See *Configuring The Spirometer and Configuration* in the Diagnostic Workstation manual.



Help – Provides on-line assistance regarding the use, operation and troubleshooting of the IQmark Diagnostic Workstation and other products.



Return to Windows – Exits the program and returns you to the Windows desktop.

E. Testing A New Patient

For a new patient, click the **New Patient** button in the opening screen. This opens the **Patient Data Entry** screen.

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Patient Data Screen

The **Patient Data** screen enables you to enter the data that is specific to your patient. Some of this data is of diagnostic value and is used by the Spirometer's interpretive program when the program analyzes the patient's data.

Each of the data fields on this screen can be accessed by clicking in it with the mouse or pressing the tab key. Although some of this information is not essential for spirometry, it is important to complete each of these fields as accurately as possible. The accuracy of, **Date of Birth, Sex, Height, and Race**, is essential since this data is used by the Spirometer interpretive analysis program to produce predicted measurements and preliminary diagnostic statements. All four digits of the year must be entered for the **Date of Birth**. The **Height** is located on the **Vital Signs** tab.

The following table provides a brief description of the function for each field. Fields that play a diagnostic role in the interpretive program are noted.

Patient Data Fields		
Field	Diagnostic Role	Description
Last Name First Name Middle Initial		Used for identification. Providing complete information facilitates easier retrieval of patient data at later dates. Either letters and/or numbers may be used.
ID		Used for identification. Either letters and/or numbers may be used.

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Patient Data Fields		
Field	Diagnostic Role	Description
Date of Birth (mm/dd/yyyy i.e. 02/14/1961)	Yes	Used for information and diagnostic analysis in Reference Values equations. Enter using a month/day/year format (this order may be changed in IQmark Configuration settings). Enter 2 digits each for month and day and all four digits for the year. The Spirometer interpretive program uses this data to calculate the age of the patient.
Sex	Yes	Used for information and diagnostic analysis in Reference Values equations. Click on the appropriate gender.
Race	Yes	Used for information and diagnostic analysis in Reference Values equations if ethnic reductions are enabled. Click on the field. A pull-down menu will then appear, allowing you to select one of several pre-labeled choices. If the patient's race is not listed, if you do not know the patient's race, or if the patient is of multiracial origin, use Appendix J for assistance.

Vital Signs tab

The Vital Signs tab displays on top when the Patient Data screen is opened. This tab enables the user to enter and track the patient's vital signs over time. The user can enter the vital signs when entering new patient information. After the patient has been saved, the user can enter additional vital signs by clicking on the **New Vital Signs** button. This clears the BP, Pulse, Temperature and SpO2 and enables you to enter new vital signs readings.

After vital sign measurements are entered, click the **Review Vital Signs** button to display all previously entered vital signs. These measurements will be display in a table as well as on a user defined graph.

The following table provides a brief description of the function for each field. Fields that play a diagnostic role in the interpretive program are noted. Additional information about the Vital Signs tab can be found in the Diagnostic Workstation Operation Manual.

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Vital Signs Tab		
Field	Diagnostic Role	Description
Weight	*	*Used for information and is used as a diagnostic tool by a physician in some cases. Use only numbers. Data may be entered in either English or Metric units, depending on which option is selected in the IQmark Configuration Settings.
Height	Yes	Used for information and diagnostic analysis in Reference Values equations. Use only numbers. Data may be entered in either English or Metric units, depending on which option you selected in the IQmark Configuration Settings.
BP (Blood Pressure)	*	*Used for information and is used as a diagnostic tool by a physician in some cases. Enter numbers only.
Pulse	*	*Used for information and is used as a diagnostic tool by a physician in some cases. Enter numbers only.
Temp.	*	*Used for information and is used as a diagnostic tool by a physician in some cases. Enter numbers only.
SpO ₂ (Pulse Oximetry)	*	*Used for information and is used as a diagnostic tool by a physician in some cases. Enter numbers only.

Smoking History		Contact Info	
Vital Signs	Medications	History	
Vital Signs			
Weight		lbs.	Temp. deg. F
Height		inches	SpO ₂ %
BP		/	
Pulse		BPM	
New Vital Signs		Review Vital Signs	

Vital Signs tab

Medications tab

Clicking the **Medication** tab displays a screen that gives you the option of adding, editing or deleting a medication from the patient's profile. Additional information about this tab can be found in the Diagnostic Workstation Operation Manual.

History tab

Clicking the **History** tab displays a screen that gives you the option of adding, editing or deleting medical history from the patient's profile. Additional information about this tab can be found in the Diagnostic Workstation Operation Manual.

Contact Info tab

Clicking the **Contact Info** tab displays a screen that gives you the option of adding, editing or deleting the patient's contact information (Address and Phone Number).

Smoking History tab

Clicking the **Smoking History** tab displays a screen that gives you the option of adding the smoking history to the patient's profile. To add this information, select the Smoker box and then enter the number of cigarettes the patient smokes per day and the number of years they have been smoking.

Vital Signs	Medications	History
Smoking History		Contact Info
☒ Smoker 20 Cigs/Day For 15 Years ☒ Quit 3 Years ago		

Smoking History tab

If the patient used to smoke and has since quit, select Smoker as above and then select the Quit box and enter the number of years since they quit.

F. Instructions for Performing a Spirometry Test

To prepare a patient for any spirometry test, you must explain to them the entire procedure for the type of test you want them to perform. Then you should demonstrate for the patient the correct procedure for performing that test. The American Thoracic Society (ATS) states in their Standardization of Spirometry 1994 Update: *“Perhaps the most important component in successful spirometry is a well-motivated, enthusiastic technician.”* Coaching and encouraging the patient with body language and with verbal language like “blast out hard and fast” and “continue to blast out” will help to ensure a good FVC maneuver with reproducible results.

Throughout of this manual, the *user* or *technician* refers to the person instructing the patient and operating the Spirometer.

The Disposable Pneumotach Mouthpiece (DPM) is designed for a single patient use. Multiple tests can be performed on one patient during one testing session. Use new DPM for each future test session on the same patient. Do not attempt to sterilize or disinfect the DPM. Any such attempts would have a high chance of affecting the results of a spirometry test. **Do not attempt to re-use the DPM.**

NOTE: **PHYSICIAN’S RESPONSIBILITY:** It is the physician’s responsibility to assure that the test is properly administered, evaluated and interpreted. The technician administering the test should have previously been trained in spirometry by completing a certified Spirometry Training course.

The instructions listed here are only a guide and should not be used to train a technician.

Prepare the patient by requiring the patient to:

- Loosen any tight articles of clothing that might constrict lung function.
- Remove any foreign objects from the mouth, including dentures if they are likely to become dislodged.
- Select a new DPM and place it in the Spirometer handle.

Once the patient is ready to perform a test, require the patient to:

- Place the lips **and teeth** around the DPM sealing their mouth to the flow sensor mouthpiece with their lips to perform any spirometry test.
- Not to block the flow tube with the tongue.
- Follow the instructions of the technician.

This Spirometer enables you to choose among FVC, VC, and MVV tests in both the Pre-Bronchodilator (Pre-BD) and Post-Bronchodilator (Post-BD) modes.

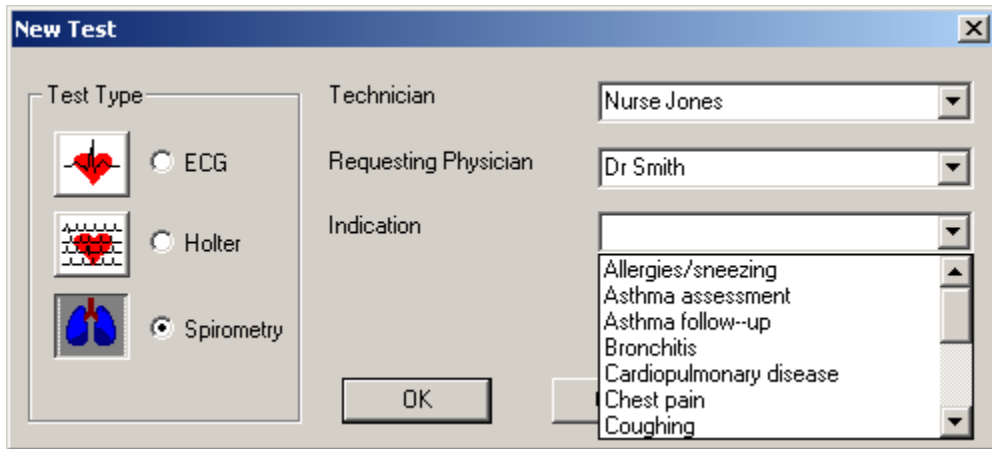
FVC or FVC Loop

The Forced Vital Capacity (FVC) test is usually the first spirometry test prescribed. The FVC test measures expiratory flow only. The FVC Loop is a FVC test with the

IQmark Digital Spirometer Operation Manual

inspiratory portion of the test included. However, a full expiratory and inspiratory loop is often referred to as a Flow Volume Loop, an FVC Loop or occasionally as an FVC test.

To start a test, click **New Test** from the New Patient screen. Enter the Technician's name and the Physician's name if desired or select them from the list. The reason for testing the patient can also be selected from a list under Indication as shown in the New Test Selection Screen below. Click on the lungs next to Spirometry and click on OK.

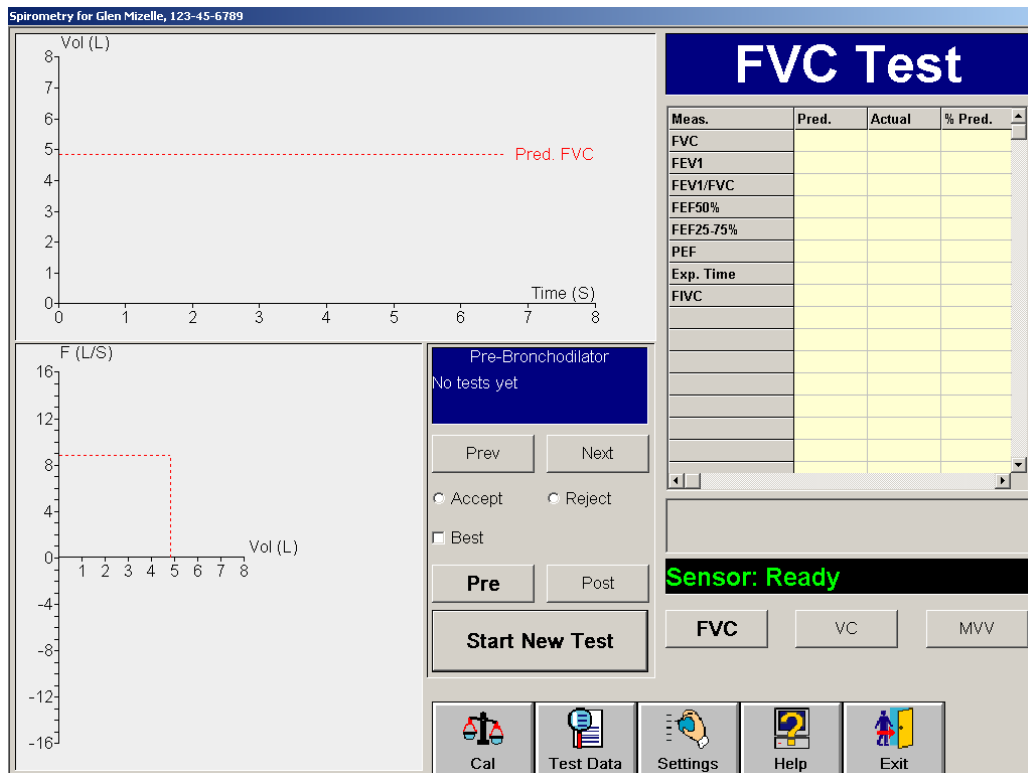


The 'New Test' window contains the following fields and options:

- Test Type:** Three radio buttons with corresponding icons: ECG (heart with line), Holter (heart with line and dots), and Spirometry (lungs). Spirometry is selected.
- Technician:** A dropdown menu showing 'Nurse Jones'.
- Requesting Physician:** A dropdown menu showing 'Dr Smith'.
- Indication:** A dropdown menu with a list of conditions: Allergies/sneezing, Asthma assessment, Asthma follow-up, Bronchitis, Cardiopulmonary disease, Chest pain, and Coughing.
- Buttons:** 'OK' and a small unlabeled button.

New Test Selection Screen

The spirometry data collection, or test, screen appears.



Spirometry Data Collection Screen

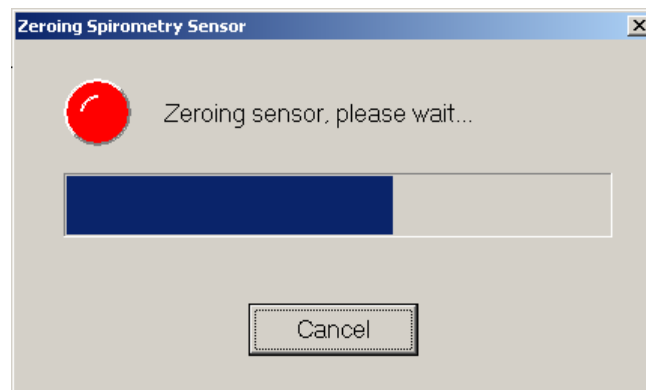
Click the **FVC** button. For a Pre-BD test, make sure the words Pre-Bronchodilator appear in the blue box in the middle of the screen. Also notice that the **Pre** button is bold. Do not click the **Start New Test** button until the patient is ready.

Once the patient is prepared, you must explain the full procedure of the test. Tell the patient to take 2 or 3 normal tidal breaths and then to inspire as deeply as possible. After a complete inhalation, tell the patient to place the flow sensor mouthpiece in their mouth and enthusiastically encourage them to blast out the air quickly and completely. Continue to encourage with voice and body language until a visible plateau is evident on the Flow-Volume scale or until the program indicates that no additional flow is being measured. If a full loop is required, instruct the patient to breathe in quickly and fully to take in as much air as possible.

Be sure to demonstrate this procedure for the patient. Let the patient see the effort required for a good test. The technician should carefully watch the entire maneuver ensuring:

- Maximal inhalation before starting
- Forced expiration - Quick, strong and without hesitation
- Continued expiration – Encourage the patient to blow out as long as possible
- Inhalation – If a flow volume loop is required, ensure that the patient takes a maximal inhalation at the end of the forced expiration.

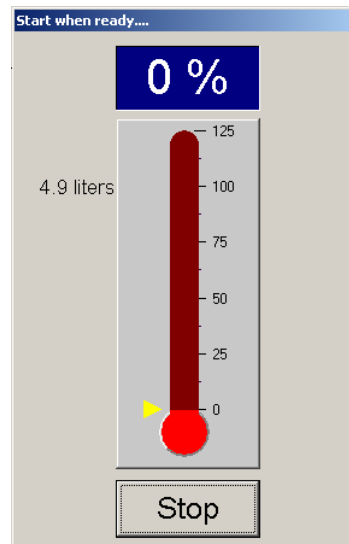
To start the test, click the Start New Test button. The device will “zero” itself. **BE SURE THAT NO AIR IS TRAVELING THROUGH THE MOUTHPIECE DURING ZEROING.** The following box will appear while the Spirometer is zeroing.



Zeroing The Sensor

Once this is done, the following display appears. Have the patient start the test.

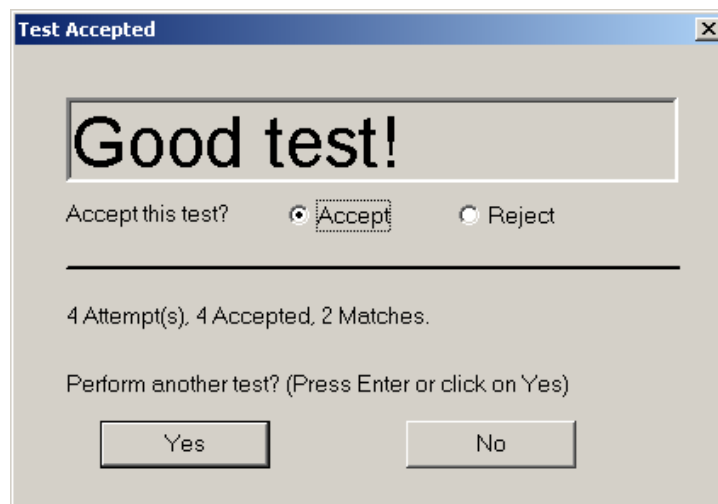
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Thermometer Incentive Display

Note that the color of the “mercury” in the thermometer changes with the percentage of the patient’s predicted FVC value. It will remain red from 0 to 49%, yellow from 51% to 79%, green from 80% to 100% and bright green above 100%. The percentage of their predicted value is also displayed above the thermometer. After the numbers have stopped rising, instruct the patient to inhale maximally or click the **Stop** button or press the **Enter** key to complete the test. Both actions will end the test.

The program automatically “grades” the test according to ATS criteria.



Test Accepted Window

After each completed test, the Test Accepted window appears. The acceptability statement is also displayed with **Accept** or **Reject** automatically selected.

IMPORTANT – The acceptability statements are only recommendations and do not mean that a tests must be accepted or rejected. It is up to you to decide if the effort performed is acceptable. You can override the software selection and choose **Accept** if you

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determine the effort is good. After deciding to accept or reject a test, click on **Yes** to perform another test or **No** to stop testing.

These acceptability statements are based on the recommendations of the ATS.

Acceptability Statements

The following table lists the acceptability statements you might see during FVC testing. Please remember, these are recommendations and not requirements. Please use your own judgment when deciding to accept or reject a test.

ATS Acceptability Statement	Criteria	On Screen Comment
Good test	Meets all the criteria listed below.	Good test!
Hesitating start	Extrapolated volume > 5% of FVC, or greater than 0.150 liters, whichever is greater.	Hesitation detected: Blast out faster; blast out harder
Test too short	Test did not last at least X seconds from start of expiration where X is the Minimum FVC Length configuration setting (default is 6 sec.)	Blow out longer
Poor effort	PEF not reached within 120ms.	Poor effort: Blast out faster; blast out harder
Interrupted flow	Cough or interruption detected.	Blast out smoothly
Abrupt stop	No plateau of duration of at least one second in which there is less than 0.050 liters of volume change.	Blast out completely
Inhalation volume is greater than the Exhalation Volume	Inhale > 1.1 * exhalation if inhalation performed.	Inhale deeper before starting the test.
Exhalation volume is greater than the Inhalation Volume	Exhale > 1.1 * inhalation if inhalation performed.	Inhale completely at the end of the test.
This acceptability statement was added by Brentwood	Volume less than 0.50 Liters	Volume Too Low

After the patient has completed the number of tests you require, click the **Save Review** button in the lower right corner. The following box will appear. Click on **Yes** to save the test results.

The dialog box titled "Save This Report?" contains a checkbox for "Delete Rejected Tests" which is checked. It displays two tables of test results. The first table, labeled "Pre-BD", shows FVC with 3 attempts, 3 accepted, and 2 matches; VC and MVV both with 0 attempts, 0 accepted, and 0 matches. The second table, labeled "Post-BD", shows FVC, VC, and MVV all with 0 attempts, 0 accepted, and 0 matches. At the bottom are "Yes", "No", and "Cancel" buttons.

Pre-BD	Attempt(s)	Accepted	Matches
FVC	3	3	2
VC	0	0	
MVV	0	0	

Post-BD	Attempt(s)	Accepted	Matches
FVC	0	0	0
VC	0	0	
MVV	0	0	

Save This Report Window

NOTE: Clicking **No** in the Save This Report window deletes all tests performed during this session. Click **YES** to save, click **CANCEL** to return to the test screen.

If you click **Yes**, the View Report screen appears. See section G of this manual for more information about the View Report screen.

If a patient's FVC is below expectations or if you suspect airways obstruction, you might require the patient to perform a slow vital capacity (SVC) or VC test.

Post-Bronchodilator Tests

The following instructions assume you have already performed the Pre-BD test on the patient and have administered the bronchodilator.

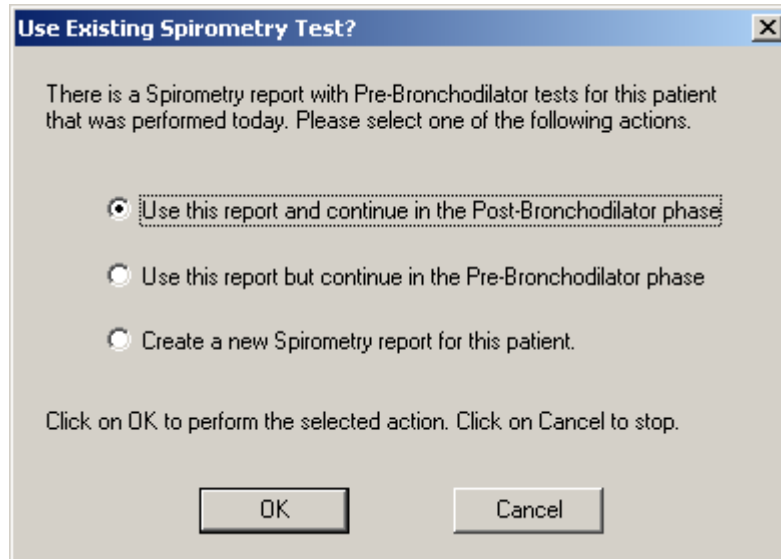
Testing one patient at a time

From the View Report screen, you can select a bronchodilator from a list and then click Post-BD to perform tests. Selecting Post-BD returns you to the testing screen. Post-BD FVC tests are performed the same way as Pre-BD FVC tests. See Appendixes P and Q.

Testing more than one patient at a time

Select a patient from the patient list. Click **New Test**. If you have performed a Pre-BD test on this patient, the program will display a list of test type selections (next page).

To attach a Post-BD test to the existing Pre-BD test, use the default setting (select the first choice) and click **OK**. This will open the testing screen. Post-BD FVC tests are performed the same way as a Pre-BD FVC tests. See Appendix P.



Existing Pre-Bronchodilator Test Window

Once the required number of Post-BD tests are performed, click the **Save Review** button to display the Pre/Post comparison.

VC or SVC

This test can determine if a patient's lungs are trapping air during a forced maneuver (FVC test). Air trapping can be an indication of airway obstruction and is also sometimes seen in older patients. This is a very slow and deliberate test. The patient takes 2 or 3 normal tidal breaths and then a slow, deep breath, and then a slow, full exhale.

Click the **VC** button. The **VC** button appears bold. If this is a Pre-BD test, make sure the Pre message is displayed in the blue box in the middle of the test screen. Do not click the **Start New Test** button until the patient is ready to perform the test.

To perform a VC test, the patient must perform the test according to the following instructions:

- Inhale completely before placing the flow sensor mouthpiece into the mouth.
- Insert the mouthpiece just past the front teeth and seal the mouth to the flow sensor mouthpiece with the lips.
- Take 3 or 4 tidal breaths with the mouthpiece in the mouth.
- Inhale as deeply as possible, until the technician observes a plateau at the bottom of the graph.
- Blow out slowly and evenly until the technician observes a plateau at the top of the graph or the device signals that the end of test criteria have been met.
- The technician should stop the test with the mouse or the ENTER key.
- Remove the mouthpiece from their mouth when instructed by the technician.

The patient must exhale at a faster rate during the “Blow out” phase than during the tidal breaths. After the patient has completed the number of tests you require, click the **Save Review** button and click **Yes** to save the test efforts.

MVV

The Maximum Voluntary Ventilation, or MVV, is the measurement of a patient’s breathing when the patient inhales and exhales maximally and rapidly for 12 to 15 seconds. The software takes this result and extrapolates the results for a period of one minute. MVV is expressed in liters per minute (L/min). This is a very demanding test and patients must be allowed to rest between efforts. The MVV test is required to qualify some patients for Social Security Disability benefits.

Click the MVV button. The MVV button now appears bold. For a Pre-BD test, make sure the Pre message is displayed in the blue box in the middle of the test screen. Do not click the **Start New Test** button until the patient is ready to perform the test.

To perform the MVV test, the patient must perform the test according to the following instructions:

- Correctly place the mouthpiece in their mouth.
- Take at least 3 normal tidal breaths.
- Inhale and exhale maximally as quickly as possible.

Coach and encourage the patient until the test time exceeds 12 seconds. Have the patient remove the mouthpiece from their mouth and allow them to rest.

After the patient has completed the number of tests you require, click the **Save Review** button and click **Yes** to save the test efforts.

G. Reviewing Patient Reports

The Diagnostic Workstation software allows for the storage of additional patient data including ECG and Holter (only if you have purchased these options). Please refer to the appropriate manual for these procedures.

H. Review Spirometry Reports

Once you have completed the spirometry session and exited the test area, View Report screen appears. The test results are displayed in the middle of the display area with other useful information displayed in the upper sections as shown in the Spirometry View Report Screens on the following page.

The name of attending technician should be entered in this screen if they have not previously been entered. Entering the Reviewed By information will CONFIRM this report. Until the Reviewed By is entered, the report is unconfirmed.

To edit or review a report, display the desired view by clicking the **Summary**, **FVC Graphs**, **MVV Graphs**, or **VC Graphs** tab. These tabs display the tests performed in the session under review. You can edit (**Technician** and **Reviewed By**), review and print the spirometry reports. Clicking the **Settings** button (upper right) enables you to select which reports to print. Remember that every report checked will print when you click the **Print** button and select **Print**.

Clicking the **Print** button and click **Print Preview** to display reports before they are printed.

Reports For Glen Mizelle

ECG | RR Variability | Holter | Spirometry | Vitals

10 - 12/21/00 12:09:33 | Report 10 of 15 | Trending

Technician: PA Smith | Review Date: 05/24/02 | Perform Pre-BD | Perform Post BD

Reviewed By: Dr. Smith | Predicteds: NHANES III | Settings | Bronchodilator: Alupent

Summary | FVC Graphs | MVV Graphs | VC Graphs

	Units	Predicted	Pre Actual	Pre % Pred.	Post Actual	Post % Pred.	% Change
FVC	L	4.984	4.532	91 %	5.062	102 %	12 %
FEV1	L	3.990	3.743	94 %	4.032	101 %	8 %
FEV1/FVC	%	80 %	83 %	103 %	80 %	100 %	-3 %
FEF25%	L/S	8.216	7.004	85 %	8.041	98 %	15 %
FEF50%	L/S	4.846	4.130	85 %	4.136	85 %	0 %
FEF75%	L/S	1.975	1.731	88 %	1.566	79 %	-9 %
FEF25-75%	L/S	3.839	3.675	96 %	3.704	96 %	1 %
PEF	L/S	9.746	8.976	92 %	9.752	100 %	9 %
Exp. Time	Sec.		7.033		8.350		19 %
V ext.	L		0.093		0.109		18 %
Best FVC	L	4.984	4.532	91 %	5.062	102 %	12 %

Interpretation

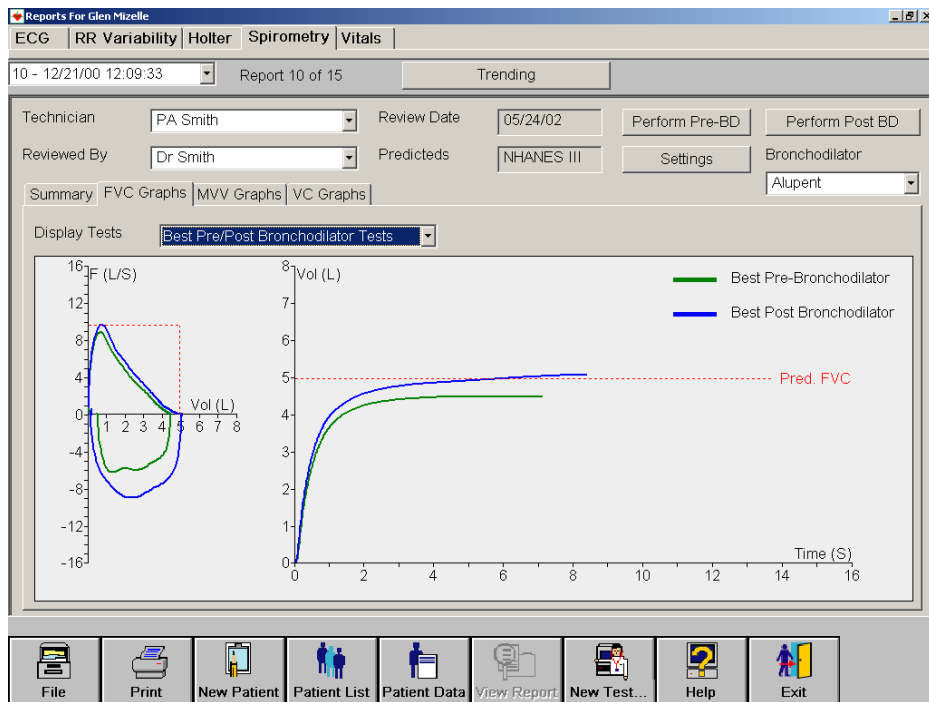
Normal spirometry. Post bronchodilator test not clearly improved.

File | Print | New Patient | Patient List | Patient Data | View Report | New Test... | Help | Exit

Spirometry View Report Screen - Summary

Click on the **Summary**, **FVC Graphs**, **MVV Graphs**, or **VC Graphs** tab to view other data for this patient. Remember that only the information stored is available for viewing, i.e., if no VC tests were performed, no VC tests are available for viewing.

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Spirometry View Report Screen – FVC Graphs

I. Printed Spirometry Reports – Analysis of results

The printed reports display patient demographics, test date and time, measurements, graphs, interpretations, and additional analysis of the spirometry test results.

COPD Risk Assessment

The COPD Risk Assessment uses the Tecumseh Index. It is helpful in smoking cessation programs. If the patient is a current smoker and that fact is entered into the Patient Data screen, the printed report will indicate the current COPD Risk and the reduced COPD risk to the patient if they quit smoking. The COPD Risk statements are: Low, Moderate, High, Risk is very high, COPD may exist.

Lung Age

The program automatically calculates the Lung Age of the patient. The Lung Age is calculated from the patient's Sex, Height and FEV₁. This estimate is also useful in smoking cessation programs. Lung Age is only calculated for patients from 20 to 84.

J. Reviewing Data for Other Patients

Patient reports can be effectively managed with the Diagnostic Workstation. You can access other patients test data by selecting the Patient List from the Patient Data screen and then clicking on Go To Report List Screen.

For additional information on the Report List screen and patient data management, refer to the Diagnostic Workstation Operation Manual.

Report List

LastName*	FirstName	ID	Report Type	Date	Time	Reviewed	Printed
Ergreg	Temo	200-05-2301	Spirometry	09/27/2001	09:24:05 AM		
Fox	Dianne	012-56-8522	ECG	10/24/2001	09:01:36 AM	10/24/2001	
Fox	Dianne	012-56-8522	ECG	10/31/2001	07:15:01 AM	10/31/2001	
Fox	Dianne	012-56-8522	ECG	11/09/2001	12:38:38 PM	04/09/2002	
Fox	Dianne	012-56-8522	ECG	07/16/2001	12:03:18 AM	07/16/2001	
Giuseppe	Soprano	812-88-6548	Spirometry	06/04/2001	02:33:58 PM		
Giuseppe	Soprano	812-88-6548	Spirometry	03/19/2001	12:24:39 PM		
Giuseppe	Soprano	812-88-6548	Spirometry	01/17/2001	05:52:40 PM	05/31/2001	
Greenwood	Edward	543-61-2308	RR Variability	02/06/2002	09:19:54 AM		
Greenwood	Edward	543-61-2308	ECG	02/06/2002	09:18:37 AM	02/06/2002	
Grind	Daily	101-66-2000	Spirometry	10/16/2000	09:46:05 AM		
Grind	Daily	101-66-2000	Spirometry	12/22/2000	03:56:22 PM		08/28/2001
Harris	January	789-58-4587	Spirometry	09/26/2001	06:11:27 PM		
Harris	January	789-58-4587	ECG	01/30/2002	02:55:27 PM		
Holman	Terry	200-05-2204	Spirometry	12/21/2000	03:08:51 PM		
Holman	Terry	200-05-2204	Spirometry	10/19/2000	10:45:29 AM		
Hu	Jack	498-84-7651	Spirometry	02/15/2001	05:04:07 PM		

Filter Reports

☐ Show Range
 From: 1/ 1/1997 To: 6/17/2002

☐ Show Today ☒ Show All

☐ Previous Month

☐ Show only reports not reviewed

Show Reports

☒ ECG ☒ Holter
☒ RR Variability ☒ Full Report
☒ Spirometry ☒ Summary Report

Show All

File Print New Patient Patient List Patient Data View Report New Test... Help Exit

Multi-Patient Report List Screen

This screen lists the patients and tests performed at your facility through the Diagnostic Workstation. It provides ID numbers, the report type, the date of each test, as well as other useful information. Use the horizontal scroll bar to view information about additional reports.

The **Filter Reports** section enables you to select reports by date and type.

In the **Show Range** area, select **Show All** to display tests from the earliest report to the current date. Select **Show Today** to display only those reports prepared on the current date according to the computer calendar. You can also indicate a range of dates using the **From** and **To** fields. The default setting is **Show All**.

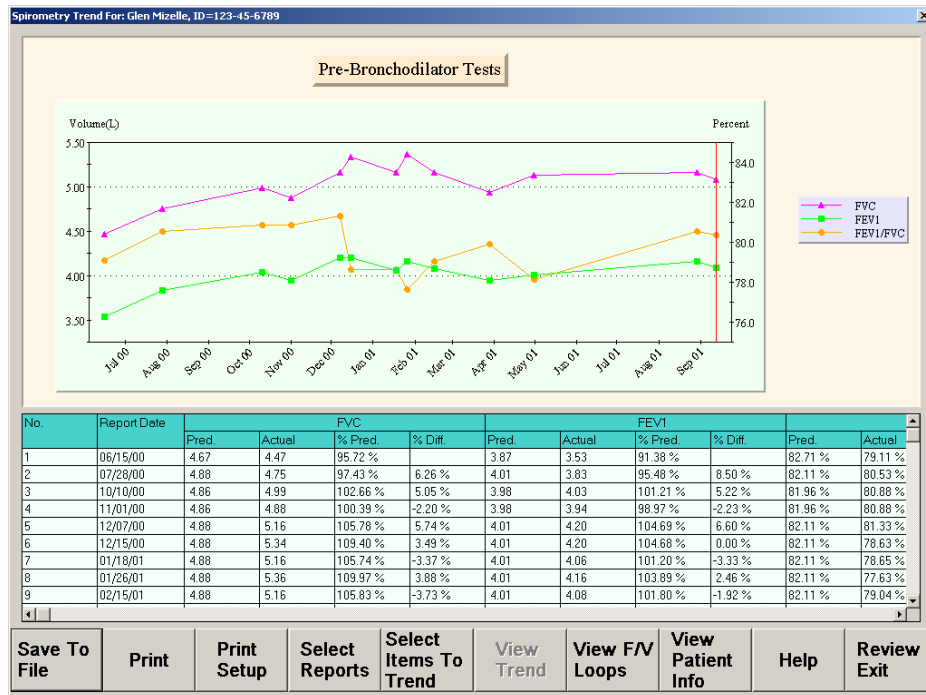
NOTE: The **From** date will not accept dates before 01/01/97.

The **Show Reports** area enables you to select one or more of the following reports for display: ECG, RR Variability, Holter, and Spirometry. Selecting **Show All** will display all available types of reports. For example, remove the check box from ECG, RR Variability and Holter to display spirometry tests only.

When the selection is completed, the **Report List** screen is updated with the new data and selection ranges.

K. Trending

Trending enables you to compare the best test measurements from two or more spirometry sessions.



Trending - Main Screen

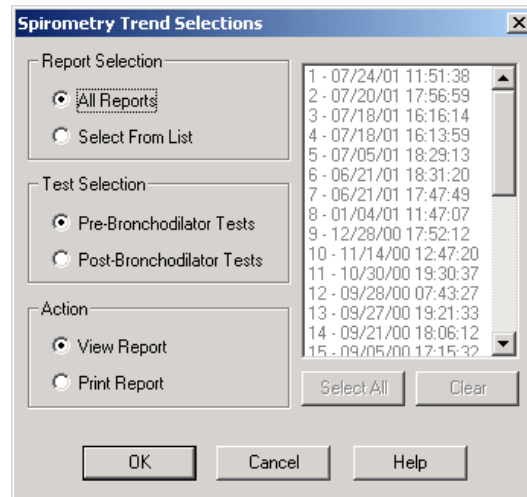
Trending enables you to compare different spirometry measurements over time so that changes in a patient's condition can be easily seen in graphical and tabular form.

The following features are standard in the Trending software:

- Select one to ten different spirometry measurements to trend at one time.
- Select the length of time to compare, from a minimum of two sessions, to any number of sessions, to all test sessions stored for a patient.
- Provide comparison between two individual tests, e.g., the best test in one session against the best test in another session.
- Provide comparison between actual and predicted measurements.
- Provide changes over a selected period of time, e.g., the oldest test session against the latest test session.
- Choose Pre-Bronchodilator tests only or Post-Bronchodilator tests only.
- Provide tabular and graphical displays for easy comparison.
- Provide color-coded graphic displays for easy identification.
- Print and display trend measurement in tabular format.
- Print and display graphical Flow/Volume (F/V) reports in overlay or side-by-side formats.

Selecting Reports to Trend

The Spirometry Trend Selection screen appears when you click the Trending button when viewing spirometry reports from the View Report screen.



Spirometry Trend Selection Window

The default settings are All Reports, Pre-Bronchodilator Tests, and View Report.

Report Selection

Select which reports to trend. First select **All Reports** or **Select From List**.

Select **All Reports** to view all the reports in the list. This is the default selection.

Select **Select From List** to select individual reports. If this option is selected, you can pick and choose which sessions to trend.

Test Selection

Select the type of tests to trend. You can trend Pre test results against Pre test results or Post test results against Post test results.

Pre-Bronchodilator -- If checked, all trended values are taken from the best Pre-BD test of the session.

Post-Bronchodilator -- If checked, all trended values are taken from the best Post-BD test of the session.

Action

This selection tells the program what to do with the trend after the above selections are chosen and the OK button is clicked.

View Report – Select to display the Trending screen. You can then choose to print the trending reports from the Trending screen.

Print Report – Select to print the trending report to the default printer when you click the OK button. The Trending screen displays briefly and then returns you to the **View Report** screen.

The **Trending** tab in **Spirometry Settings** enables you to select the parameters to trend, the type of Flow Volume Loop report to print and the default Flow Volume Loop to display.

The left axis and right axis scales are independent of each other. The left axis always displays volume parameters in liters. The right axis displays either percentage parameters or flow parameters.

Spirometry Settings - Trending

Volume Parameters

Measurements -- Lists volume measurements selected for the left axis.

Predicted -- Lists predicted values for volume measurements for the left axis.

Flow and Percentage Parameters

None -- Disables the right axis trend.

Flow -- If selected, the right axis is for trending flow measurements.

Percent -- If selected, the right axis is for trending percentage measurements.

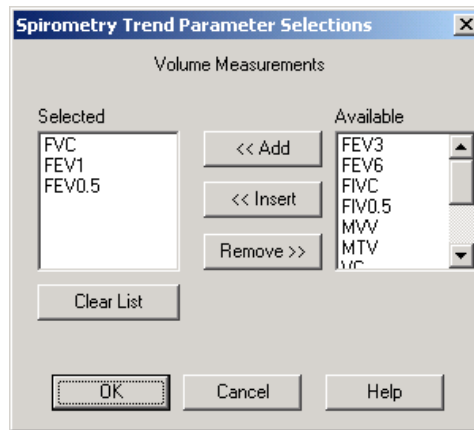
Measurements -- Lists flow or percentage measurements selected for the right axis.

Predicted -- Lists predicted values for flow or percentage measurements for the right axis.

Selecting Parameters to Trend

This dialog box enables you to select which parameters to trend. There are six possible sets of parameters. They are:

1. Volume measurements
2. Volume predicted values
3. Percentage measurements
4. Percentage predicted values
5. Flow measurements
6. Flow predicted values



Spirometry Trend Parameter Selection

From the Trending tab in Spirometry Settings, click the **Select** button. The Spirometry Trend Parameters box displays. To add an item to the **Selected** box, select the item in the **Available** box and click the **Add** button. This will place the new item at the bottom of the list.

To insert an item between or above items in the **Selected** box, select the item in the **Selected** box above which you want to place a new item, select an item from the **Available** box, and click the **Insert** button.

To remove an item from the **Selected** box, select the item to be removed and click the **Remove** button.

To start a new list with no items selected, click the **Clear List** button.

Report Selection

Select which type of Flow Volume Loops you want to print when the trend report is printed.

Side By Side F/V Loops -- If checked, the F/V Loops are displayed and printed side-by-side.

Overlay F/V Loops -- If checked, the F/V Loops are displayed and printed overlaid.

Default F/V Display

Select which type of Flow Volume Loops you want to see when the trend report is displayed.

Side By Side -- If selected, the Side By Side F/V Loop screen is displayed as the default when you click on the View F/V Loops button in the Trending screen.

Overlay -- If selected, the Overlay F/V Loop screen is displayed as the default when you click on the View F/V Loops button in the Trending screen.

Total Selected -- Indicates the total number of parameters selected for printing.

Maximum Allowed -- Displays the maximum number of parameters allowed .

Trend Display Screen

The Trending screen is the main screen of the Spirometry trending control. It consists of a graphical trending chart, a tabular measurement grid, and trending button bar.

The graphical chart plots volume parameters on the left axis. The right axis is optional and can display either percentage parameters or flow parameters, depending on the settings. The horizontal axis represents time, spanning from the earliest session to the latest session.

Each parameter trended is a data series and is built from the values from the best Pre-BD or best Post-BD test of the spirometry sessions selected. The graph created for each parameter is represented by a different color line.

A vertical marker on the display moves left or right as you move the cursor from left to right. The software will automatically scrolls the grid and highlights the report to which the current marker points. Also, if you click on a grid row, the software moves the vertical marker to the data corresponding to the selected report.

Save To File	Print	Print Setup	Select Reports	Select Items To Trend	View Trend	View F/V Loops	View Patient Info	Help	Review Exit
--------------	-------	-------------	----------------	-----------------------	------------	----------------	-------------------	------	-------------

Trending Button Bar

Save To File – Click to open the File Save dialog box. If a valid filename is entered and the OK button is clicked, the software saves the information in the grid to a file in Microsoft Excel (*.xls) file format.

Print – Click to print the trend report to the currently selected printer.

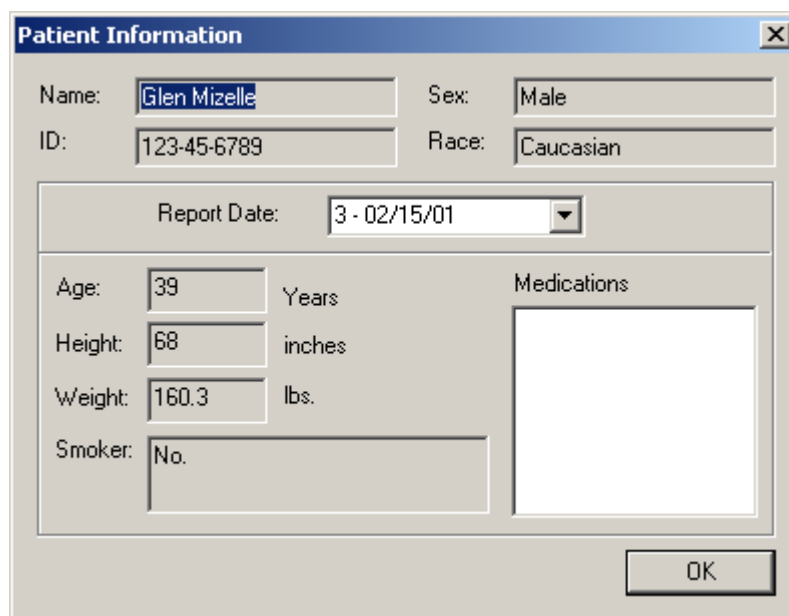
Print Setup – Click to display the Windows printer setup box.

Select Reports – Click to close this screen and return to the Spirometry Trend Selection Screen.

Select Items To Trend – Click to display the Trending tab from Spirometry Settings.

View F/V Loops – Click to display the Flow/Volume loops using the default screen format or the last screen format used.

View Patient Info – Click to display the patient's information for the current highlighted test.



The image shows a 'Patient Information' dialog box with a blue title bar and a close button (X) in the top right corner. The form contains several input fields: 'Name' with the text 'Glen Mizelle', 'Sex' with 'Male', 'ID' with '123-45-6789', and 'Race' with 'Caucasian'. Below these is a 'Report Date' field showing '3 - 02/15/01' with a dropdown arrow. Further down, there are fields for 'Age' (39), 'Years', 'Height' (68), 'inches', 'Weight' (160.3), 'lbs.', and 'Smoker' (No.). To the right of these fields is a large empty box labeled 'Medications'. An 'OK' button is located at the bottom right of the dialog.

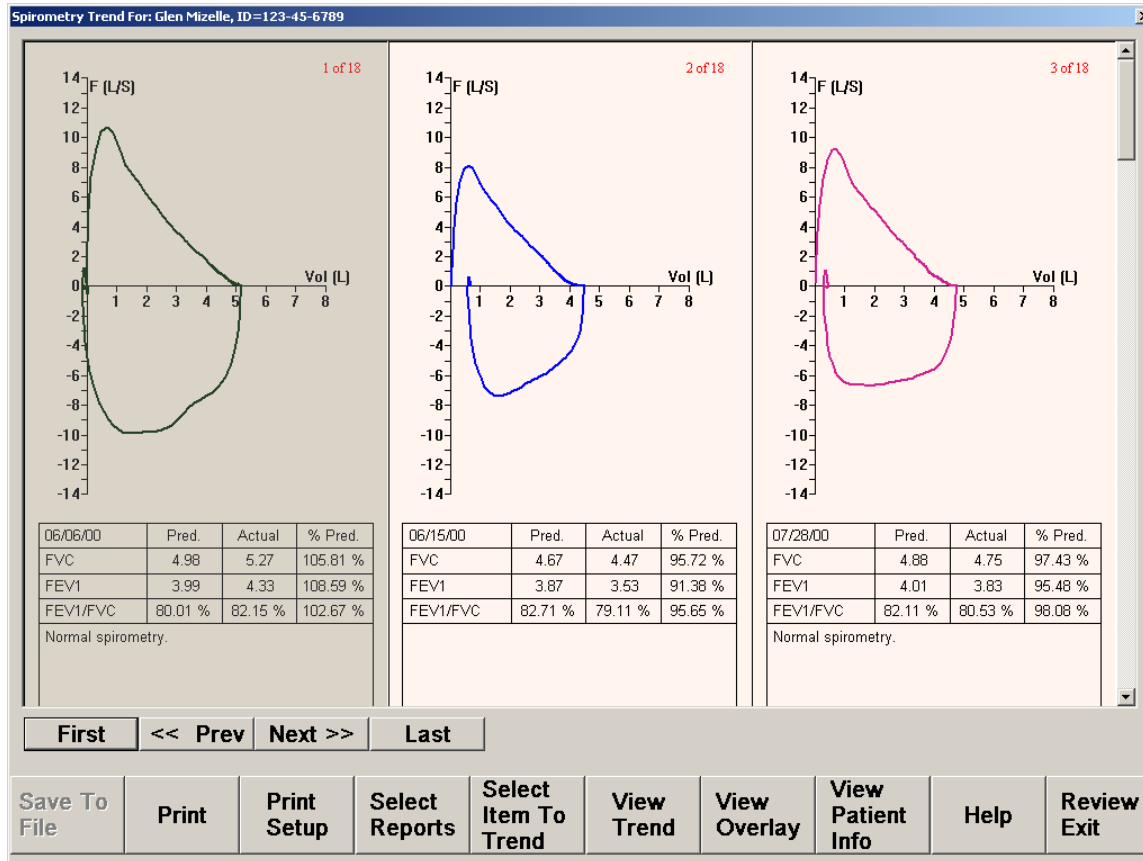
Patient Information

Help – Click to open the Help file.

Review/Exit – Click to exit this screen and return to the View Report screen.

Side by Side F/V Loops

This screen shows three F/V loops at a time, with the loop to the left representing the oldest and each newer test to the right and then below.



Side By Side Screen

Immediately below the display are buttons that provide fast navigation:



First – Display the first, second, and third F/V loops.

Previous – Shift the display to show the previous series of F/V loops.

Next – Shift the display to show the next series of F/V loops.

Last – Display the last F/V loops.

Click the View Overlay button to display the F/V loops in an overlay format.

The Overlay F/V Loop screen consists of a single F/V graphical display of the best FVC loop from each trended session, a chart showing the trended plots, and a tabular grid showing the parameters trended.



When you move the vertical marker to a date or select a point in the grid, the software highlights the F/V loop corresponding to that report (if one exists) by drawing the loop in a darker color. The loop returns to its previous color when you select another report.

IV. Appendix

A. Screen Summary

Summary of Screens

Summary of Screens		
Screen Name	Screen Summary	Main Functions
Opening Screen	Enables you to access the main functions of the Diagnostic Workstation.	• Access New Patient screen. • Access Patient List screen. • Access online Help. • Exit to Windows desktop.
Patient Data Entry screen	Contains data fields for patient information including name, ID, vital signs, medications, smoking and medical history.	• Enter essential patient data. • Edit data for an existing patient. • Initiate test for a new patient.
Patient List screen	Shows a list of all patients in the database.	• Update patient data for selected patient. • Register a new patient. • Search for specific patient using their name, ID and other criteria. • Delete selected patient records. • Restore archived reports.

Summary of Screens		
Screen Name	Screen Summary	Main Functions
Report List screen	Shows a list of all reports for all patients.	• Select report to review. • Print one or more selected reports. • Restore and archived reports. • Search for a patient using name or ID. • The File button enables you to: ○ Delete currently viewed report. ○ Restore (retrieve) archived reports. ○ Archive reports. ○ Send currently viewed report by email.
Spirometry Test Screen	Used to acquire spirometry tests. Also used to accept or reject tests and assign the best test of a session	• Acquires FVC, VC and MVV tests. • Automatically “grades” tests based on the ATS recommendations. • Compares accepted tests for reproducibility. • Enables the user to change the settings for the spirometer.
Spirometry Review Screen	Shows the interpretation for the best Pre-FVC test. Allows the user to confirm the test interpretation.	• View and analyze the spirometry test numeric and graphic results. • Enables the user to print preview the test report. • Enables the user to edit the interpretation. • Enables the user to change the settings for the spirometer.

B. Spirometry Testing at a Glance

A condensed guide to using the IQmark Digital Spirometer with new patients.

The ATS recommends that calibration be performed daily before testing is started.

- 1) Start the **Diagnostic Workstation** program.
- 2) Select **New Patient** from the opening screen.
- 3) Complete the Name, Date of Birth, Weight, Height, Sex, and Race fields on the screen.
- 4) When the Patient Data screen is complete, select **New Test**
- 5) Select **Spirometry** and then click **OK**.
- 6) Prepare the patient for the spirometry test. Select a new disposable mouthpiece.
- 7) The type of test currently selected is displayed in bold in the upper right corner of the screen. If this is not the type of test required, select the required test by clicking the appropriate button – FVC, VC, MVV, and either Pre or Post.
- 8) When the patient is ready, click **Start New Test**.
- 9) Wait while the sensor automatically zeros the sensor – DO NOT ALLOW AIRFLOW TO PASS THROUGH THE SENSOR DURING THIS PROCESS.
- 10) When the incentive box displays “Start When Ready” instruct the patient to begin the test.
- 11) Encourage the patient with verbal and body language to perform the test properly. For an FVC test, you can ask them to blast out fast and blow out long.
- 12) Click the **Stop** button to conclude the test and review the current data.
- 13) Repeat steps 7 through 12 until you have acquired the number of tests desired.
- 14) Click on **Save** to save tests and review or print the data.
- 15) Discard the used mouthpiece after all tests are completed.

C. Troubleshooting

This Troubleshooting Guide provides a list of solutions or recommendations to problems that you may encounter with the Diagnostic Workstation. Before calling Brentwood Medical Technology for Technical Support, please refer to the following table for help. Error messages are displayed at the center or at the bottom right corner of the screen.

Troubleshooting Guide

Troubleshooting Guide	
Error Message or Problem	Solution or Recommendation
View Report screen does not work	• Exit Diagnostic Workstation. • Start MS-DOS Prompt (command). • Change directory to c:\windows\system (if Windows NT, c:\winnt\system32) • Type <code>regsvr32 msflxgrd.ocx</code> and press Enter • Type <code>regsvr32 oleaut32.dll</code> and press Enter • Exit MS-DOS Prompt and re-start Workstation.
MODULE NOT RESPONDING! Or SENSOR NOT RESPONDING! Message appears after starting New Test. No waveform is displayed on the screen.	IQmark Digital Spirometer cannot communicate with the computer because the handle is not connected to the computer, the handle is connected to the wrong serial port, or the batteries are completely dead or installed incorrectly. • Verify the cable is connected to a serial port and that it is the correct serial port (COM1 or COM2). • Check battery orientation or install new batteries.
FAILED TO CREATE EMPTY DOCUMENT Message appears immediately after initial software installation and after each attempt to start the Diagnostic Workstation.	All Windows programs must be closed before the installation of Diagnostic Workstation. • Uninstall the Diagnostic Workstation, restart computer and reinstall the Diagnostic Workstation (refer to the Diagnostic Workstation Operation Manual).
Incorrect diagnostic interpretation.	• Check Patient's Date of Birth, Height, Sex, and other demographics to ensure the information is accurately entered. • Check which Pre-FVC test is selected as the best test. • Check which Interpretation Logic is selected.

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The [test] report dated [test date] for [patient name] is in use by [network computer name] Message appears when trying to open a specific test report.	This Report Locking feature prevents more than one user from accessing the same report at the same time, specifically in a LAN environment where different workstations are sharing the central database. Report Locking can also be caused by improperly exiting the patient report from any workstation. • Close the desired test report for the specific patient at the [network computer name] workstation using the Review Exit button
This patient's record is in use by: [network computer name] Message appears when trying to open a specific Patient Data screen.	This Record Locking feature prevents more than one user from accessing the same patient record at the same time, specifically in a LAN environment where different workstations are sharing the central database. Record Locking can also be caused by improperly exiting the Patient Data screen from any workstation. • Close the specific Patient Data screen at the [network computer name] workstation using the Opening Screen button.
Unable to create big button Message appears when attempting to launch/start Diagnostic Workstation.	• Click on the 'X' close button on the top right corner to exit Diagnostic Workstation. • Start MS-DOS Prompt. • Change directory to c:\windows\system (if Windows NT, c:\winnt\system32) • Type <code>regsvr32 threed32.ocx</code> and press Enter • Exit MS-DOS Prompt and start Diagnostic Workstation.
Other operation problems...	• Please refer to the online help by clicking on the Help button at any screen. • Contact Brentwood Customer Support. See contact information at the end of this manual.
Predicted FEV₁/FVC is not available or valid.	• Check patient demographics. Race, Age, Sex, and Height (R.A.S.H.) must be entered to calculate a Predicted Value.

D. Maintenance and Storage

Cleaning

CAUTION

Do not use aromatic hydrocarbons, rubbing alcohol, or solvents for cleaning the Spirometer.

Preventative Cleaning

Clean the outside of the Spirometer handle with a mild solution of detergent and water on a soft cloth. Do not use an excessive amount of solution. Be sure not to wet the connectors on the top or the battery compartment at the bottom. If necessary, use a mild sterilizing detergent generally used in hospitals with low alcohol content. **Verify that all equipment, including accessories, is completely dry before using.**

Preventative Inspection

A preventative inspection should be done prior to each use. This is done to verify that there is no visible damage to the unit that may cause it to malfunction.

Visual inspection should include the handle and the cable for signs of damage and deterioration, including but not limited to cracks, cuts, discoloration, or oxidation. If a cable or other accessory exhibits any of these symptoms, call Brentwood Customer Support.

Storage

To prevent damage to the Spirometry Module due to battery leakage or oxidation, remove all batteries if the Spirometry Module is not to be used or is to be stored for long period of time. Avoid extreme humidity and heat during storage.

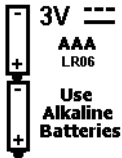
Radio and Television Interference

This equipment does not generate or use radio frequency energy. It will not cause interference to radio or television reception.

This equipment has been tested and proved to be in compliance with the limits for a medical device in accordance with the IEC 60601 rules, which are designed to provide reasonable protection against such interference in a medical or hospital environment.

E. Safety and International Symbols

The following symbols are used on Brentwood products. Refer to this directory for details concerning the symbols used on equipment.

Symbol	Description
	ATTENTION – Refer to manual for instructions.
	Year manufactured.
	Do Not Use For More Than One Patient – Single Patient Use Only, but multiple tests can be performed on the same patient with a single mouthpiece.
	IEC 601-1 Medical Electric Equipment - Type BF Equipment Equipment displaying this symbol provides the patient protection by providing isolation from earthed parts and other accessible parts of the equipment.
	Battery orientation, battery type, and power requirements.
	ETL Listing Mark Equipment displaying this symbol has been tested to comply with the following safety standards: UL STD 2601-1; CAN/CSA STD C22.2 601.1-M90
	CE Mark. Equipment displaying this symbol has passed specific safety tests and adheres to international quality standards originated from the European Community.

F. Interpretation – ATS

The American Thoracic Society (ATS) created recommendations for the interpretation of spirometry tests. Measurements are compared to the Lower Limit of Normal (LLN).

The IQmark Digital Spirometer software displays the statement "Normal spirometry" if the FVC and the FEV1/FVC ratio are within the normal range (i.e., above the LLN).

Airway Obstruction - If the FEV1/FVC ratio is below the LLN, the software displays one of the following statements regarding obstruction.

Statement	Criteria
Obstruction may be a physiological variant.	FEV1 $\geq$ 100% Pred. FEV1
Mild obstruction.	70% Pred. FEV1 $\leq$ FEV1 < 100% Pred. FEV1
Moderate obstruction.	60% Pred. FEV1 $\leq$ FEV1 < 70% Pred. FEV1
Moderately severe obstruction.	50% Pred. FEV1 $\leq$ FEV1 < 60% Pred. FEV1
Severe obstruction.	34% Pred. FEV1 $\leq$ FEV1 < 50% Pred. FEV1
Very severe obstruction.	FEV1 < 34% Pred. FEV1

If the FVC is below the LLN, the software will add, "with low vital capacity" to the above obstruction statements.

Lung Restriction - If there is no suggested airway obstruction, the program displays one of the following statements pertaining to lung restriction.

Statement	Criteria
Mild restriction.	70% Pred. FVC $\leq$ FVC < LLN
Moderate restriction.	60% Pred. FVC $\leq$ FVC < 70% Pred. FVC
Moderately severe restriction.	50% Pred. FVC $\leq$ FVC < 60% Pred. FVC
Severe restriction.	34% Pred. FVC $\leq$ FVC < 50% Pred. FVC
Very severe restriction.	FVC < 34% Pred. FVC

Pre/Post Bronchodilator Comparison - If both pre and post bronchodilator tests have been performed, the software performs and reports automatic interpretation for both sets of test data.

Statement	Ratio of Post-BD / Pre-BD (Post/Pre)	
	Post FVC/Pre FVC	Or Post FEV1/Pre FEV1
Markedly improved	≥ 1.25	≥ 1.25
Improved	1.15 to 1.24	1.12 to 1.24
Not clearly improved	1.05 to 1.14	1.05 to 1.11
Not improved	< 1.05	< 1.05

G. Interpretation – NHANES III

The 3rd National Health And Nutrition Examination Survey (NHANES III) created a number of medical recommendations including some directed at spirometry. A new set of predicted equations as well as new calculations for LLN (lower limit of normal) were developed from data collected and we have labeled these equations as NHANES III.

The National Lung Health Education Program (NLHEP) published an Interpretation table using NHANES III. We have labeled this interpretation logic as NHANES III. It determines results as follows:

The software displays a statement that reads "Normal spirometry" if the FEV_1 and the FEV_1/FEV_6 ratio are within the normal range (i.e. above the LLN).

If the FEV_1/FEV_6 ratio and the FEV_1 are below the LLN, the software will display one of the following statements regarding obstruction.

Statement	Criteria
Mild obstruction.	$FEV_1 \geq 60\% \text{ Pred. } FEV_1$
Moderate obstruction.	$40\% \text{ Pred. } FEV_1 \leq FEV_1 < 60\% \text{ Pred. } FEV_1$
Severe obstruction.	$FEV_1 < 40\% \text{ Pred. } FEV_1$

In addition, if the FEV_1/FEV_6 ratio is above the LLN but the FEV_6 measurement is below the LLN, the software will output the following statement:

"Low vital capacity, perhaps due to restriction of lung volumes"

H. Reference Values - Adult

The IQmark Digital Spirometer software provides the following sets of reference equations for adult patients.

1. Crapo (Crapo/Knudson compilation, aka ITS, ATS)
2. Knudson (1976 & 1983 compilation)
3. European Community For Coal And Steel (ECCS) (1993)
4. NHANES III (aka NLHEP, Hankinson)
5. Morris
6. Roca

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Crapo - Adult

Height (H) is in centimeters. Age (A) is in years.

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
VC	M/F	W	All	Predicted VC = Predicted FVC			
FVC	M	W	15–91	$0.06H - 0.0214A - 4.650$	0.644	1.115	Ref. 4
	F	W	15–91	$0.0491H - 0.0216A - 3.590$	0.393	0.676	Ref. 4
FEV _{0.5}	M	W	15–91	$0.0327H - 0.0152A - 1.914$	0.414	0.708	Ref. 4
	F	W	15–91	$0.0238H - 0.0185A - 0.809$	0.294	0.506	Ref. 4
FEV ₁	M	W	15–91	$0.0414H - 0.0244A - 2.190$	0.486	0.842	Ref. 4
	F	W	15–91	$0.0342H - 0.0255A - 1.578$	0.326	0.561	Ref. 4
FEV ₃	M	W	15–91	$0.0535H - 0.0271A - 3.512$	0.587	1.017	Ref. 4
	F	W	15–91	$0.0442H - 0.0257A - 2.745$	0.360	0.620	Ref. 4
FEV ₁ /FVC%	M	W	15–91	$-0.13H - 0.152A + 110.49$	4.78	8.28	Ref. 4
	F	W	15–91	$-0.202H - 0.252A + 126.58$	5.26	9.06	Ref. 4
FEV ₃ /FVC%	M	W	15–91	$-0.0627 - 0.145A + 112.09$	2.68	4.64	Ref. 4
	F	W	15–91	$-0.0937H - 0.163A + 118.16$	3.11	5.36	Ref. 4
FEF _{25-75%}	M	W	15–91	$0.0204H - 0.038A + 2.133$	0.962	1.666	Ref. 4
	F	W	15–91	$0.0154H - 0.046A + 2.683$	0.792	1.363	Ref. 4

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Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
PEF	M	W	18-25	$0.0780H + 0.1660A - 8.060$	1.653	2.72	Ref. 14
	M	W	25-85	$0.0940H - 0.0350A - 5.993$	2.078	3.42	“
	F	W	20-87	$0.0490H - 0.0250A - 0.735$	1.605	2.64	“
FEF _{25%} (MEF _{75%})	M	W	18-25	$0.0700H + 0.1470A - 7.054$	1.530	2.52	Ref. 14
	M	W	25-85	$0.0880H - 0.0350A - 5.618$	2.012	3.31	“
	F	W	20-87	$0.0430H - 0.0250A - 0.132$	1.53	2.52	“
FEF _{50%} (MEF _{50%})	M	W	18-24	$0.0543H + 0.1150A - 6.3851$	1.1196	1.184	Ref. 13
	M	W	25-85	$0.0684H - 0.0366A - 5.5409$	1.2915	2.12	“
	F	W	20-70	$0.0321H - 0.0240A - 0.4371$	0.9778	1.61	“
	F	W	70-87	$0.0118H - 0.0755A + 6.2402$	0.7569	1.25	“
FEF _{75%} (MEF _{25%})	M	W	18-25	$0.0397H - 0.0057A - 4.2421$	0.7551	1.24	Ref. 13
	M	W	25-85	$0.0310H - 0.0230A - 2.4827$	0.6917	1.14	“
	F	W	20-70	$0.0174H - 0.0254A - 0.1822$	0.6612	1.09	“
	F	W	70-90	$-0.0172A + 1.8894$	0.2409	0.396	“
MVV	M	W	18-25	$1.840H + 1.800A - 192.3$			K3
	M	W	25-85	$2.080H - 1.0800A - 168.1$			K3
	F	W	20-87	$1.090H - 0.840A - 31.8$			K3

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	15 – 91	157 – 194	62 – 76
Female	17 – 84	146 – 178	57 – 70

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Knudson - Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
VC	M/F	W	All	Predicted VC = Predicted FVC			
FVC	M	W	18-25	$0.0590H + 0.0739A - 6.8865$	0.4708	0.775	Ref. 13
	M	W	25-85	$0.0844H - 0.0298A - 8.7818$	0.6384	1.05	“
	F	W	20-70	$0.0444H - 0.0169A - 3.1947$	0.4831	0.795	“
	F	W	70-90	$0.0313H - 0.0296A - 0.1889$	0.5745	0.945	“
FEV _{0.5}	M	W	18-25	$0.030H + 0.043A - 3.0540$	0.425	0.699	Ref. 14
	M	W	25-85	$0.037H - 0.017A - 2.746$	0.474	0.779	“
	F	W	20-87	$0.019H - 0.014A - 0.406$	0.388	0.638	“
FEV ₁	M	W	18-25	$0.0519H + 0.0636H - 6.1181$	0.4458	0.734	Ref. 13
	M	W	25-85	$0.0665H - 0.0292A - 6.5147$	0.5241	0.862	“
	F	W	20-70	$0.0332H - 0.0190A - 1.8210$	0.3903	0.642	“
	F	W	70-90	$0.143H - 0.0397A + 2.6539$	0.3758	0.618	“
FEV ₃	M	W	18-25	$0.052H + 0.066A - 5.531$	0.589	0.969	Ref. 14
	M	W	25-85	$0.063H - 0.031A - 5.245$	0.575	0.946	“
	F	W	20-87	$0.035H - 0.023A - 1.633$	0.496	0.816	“
FEV ₁ /FVC%	M	W	18-25	$-0.0813H + 100.4389$	6.5752	10.82	Ref. 13
	M	W	25-85	$-0.105A + 86.6862$	6.2691	10.31	“
	F	W	20-89	$-0.1852H - 0.1896A + 121.6777$	7.5702	12.45	“
FEF _{25-75%}	M	W	18-25	$0.0539H + 0.0749A - 6.1990$	0.9861	1.62	Ref. 14
	M	W	25-85	$0.0579H - 0.0363A - 4.5175$	1.0825	1.78	“
	F	W	20-70	$0.0300H - 0.0309A - 0.4057$	0.8539	1.40	“
	F	W	70-90	$-0.0615A + 6.3706$	0.7210	1.19	“
PEF	M	W	18-25	$0.0780H + 0.1660A - 8.060$	1.653	2.72	Ref. 14
	M	W	25-85	$0.0940H - 0.0350A - 5.993$	2.078	3.42	“
	F	W	20-87	$0.0490H - 0.0250A - 0.735$	1.605	2.64	“

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FEF _{25%} (MEF _{75%})	M	W	18-25	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 14
	M	W	25-85	0.0880H - 0.0350A - 5.618	2.012	3.31	“
	F	W	20-87	0.0430H - 0.0250A - 0.132	1.53	2.52	“
FEF _{50%} (MEF _{50%})	M	W	18-24	0.0543H + 0.1150A - 6.3851	1.1196	1.184	Ref. 13
	M	W	25-85	0.0684H - 0.0366A - 5.5409	1.2915	2.12	“
	F	W	20-70	0.0321H - 0.0240A - 0.4371	0.9778	1.61	“
	F	W	70-87	0.0118H - 0.0755A + 6.2402	0.7569	1.25	“
FEF _{75%} (MEF _{25%})	M	W	18-25	0.0397H - 0.0057A - 4.2421	0.7551	1.24	Ref. 13
	M	W	25-85	0.0310H - 0.0230A - 2.4827	0.6917	1.14	“
	F	W	20-70	0.0174H - 0.0254A - 0.1822	0.6612	1.09	“
	F	W	70-90	-0.0172A + 1.8894	0.2409	0.396	“
MVV	M	W	18-25	1.840H + 1.800A - 192.3			K3
	M	W	25-85	2.080H - 1.0800A - 168.1			K3
	F	W	20-87	1.090H - 0.840A - 31.8			K3

Notes:

1. CI_{95%} calculated using the equation $CI_{95\%} = 1.645 * SEE$.
2. Race: W = white. Sex: M = male, F = female.
3. A = age in years. H = height in centimeters.
4. Height ranges are as follows

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	18-25	139.7-195.6	55-77
Male	25-85	157.5-195.6	62-77
Female	20-70	147.3-180.3	58-71
Female	70-90	147.3-167.3	58-66

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European Community For Coal And Steel (ECCS) - Adult

The following reference values are from Reference 11.

Height (H) is in meters. Age (A) is in years.

Parameter	Sex	Race	Age See Note 1	Predicted Equation	RSD	CI _{95%} See Note 2
VC	M	W	18-70	$6.10H - 0.028A - 4.65$	0.56	0.92
	F	W	18-70	$4.66H - 0.026A - 3.28$	0.42	0.69
FVC	M	W	18-70	$5.76H - 0.026A - 4.34$	0.61	1.00
	F	W	18-70	$4.43H - 0.026A - 2.89$	0.43	0.707
FEV ₁	M	W	18-70	$4.30H - 0.029A - 2.49$	0.51	0.839
	F	W	18-70	$3.95H - 0.025A - 2.60$	0.38	0.625
FEV ₁ /VC%	M	W	18-70	$-0.18A + 87.21$	7.17	11.79
	F	W	18-70	$-0.192A + 89.10$	6.51	10.7
FEF _{25-75%}	M	W	18-70	$1.94H - 0.043A + 2.70$	1.04	1.71
	F	W	18-70	$1.25H - 0.034A + 2.92$	0.85	1.398
PEF	M	W	18-70	$6.14H - 0.043A + 0.15$	1.21	1.99
	F	W	18-70	$5.50H - 0.030A - 1.11$	0.90	1.48
FEF _{25%}	M	W	18-70	$5.46H - 0.029A - 0.470$	1.71	2.81
(MEF _{75%})	F	W	18-70	$3.22H - 0.025A + 1.60$	1.35	2.22
FEF _{50%}	M	W	18-70	$3.79H - 0.031A - 0.35$	1.32	2.17
(MEF _{50%})	F	W	18-70	$2.45H - 0.025A + 1.16$	1.10	1.81
FEF _{75%}	M	W	18-70	$2.61H - 0.026A - 1.34$	0.78	1.28
(MEF _{25%})	F	W	18-70	$1.050H - 0.025A + 1.11$	0.69	1.14
MVV	M	W	18-70	$1.34H \times 100 - 1.26A - 21.40$		Kory
	F	W	18-70	$0.807H \times 100 - 0.57A - 5.50$		Lindall

Notes:

1. If the patient age is between 18 and 25, the program shall use the equation for age = 25.
2. CI_{95%} calculated using the equation $CI_{95\%} = 1.645 * RSD$.

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NHANES III (Hankinson, NLHEP) - Adult

Male age range : ≥ 18 yearsFemale age range: ≥ 20 years

Parameter	Sex	Race	Intercept	Age	Age ²	Ht _{prd} (cm) ²	Ht _{ln} (cm) ²
			b ₀	b ₁	b ₂	b ₃	b ₃
FVC	M	W	-0.1933	0.00064	-0.000269	0.00018642	0.00015695
	M	B	-0.1517	-0.01821	0	0.00016643	0.00013670
	M	H	0.2376	-0.00891	-0.000182	0.00017823	0.00014947
	F	W	-0.3560	0.01870	-0.000382	0.00014815	0.00012198
	F	B	-0.3039	0.00536	-0.000265	0.00013606	0.00010916
	F	H	0.1210	0.00307	-0.000237	0.00014246	0.00011570
FEV ₁	M	W	0.5536	-0.01303	-0.000172	0.00014098	0.00011607
	M	B	0.3411	-0.02309	0	0.00013194	0.00010561
	M	H	0.6306	-0.02928	0	0.00015104	0.00012670
	F	W	0.4333	-0.00361	-0.000194	0.00011496	0.00009283
	F	B	0.3433	-0.01283	-0.000097	0.00010846	0.00008546
	F	H	0.4529	-0.01178	-0.000113	0.00012154	0.00009890
FEV ₆	M	W	0.1102	-0.00842	-0.000223	0.00018188	0.00015323
	M	B	-0.0547	-0.02144	0	0.00016429	0.00013499
	M	H	0.5757	-0.02860	0	0.00017840	0.00015029
	F	W	-0.1373	0.01317	-0.000352	0.00014395	0.00011827
	F	B	-0.1981	0.00047	-0.000230	0.00013497	0.00010848
	F	H	0.2033	0.00020	-0.000232	0.00014106	0.00011480
PEF	M	W	1.0523	0.08272	-0.001301	0.00024962	0.00017635
	M	B	2.2257	-0.04082	0	0.00027333	0.00018938
	M	H	0.0870	0.06580	-0.001195	0.00030243	0.00021833
	F	W	0.9267	0.06929	-0.001031	0.00018623	0.00012148
	F	B	1.3597	0.03458	-0.00847	0.00019746	0.00012160
	F	H	0.2401	0.06174	-0.001023	0.00022203	0.00014611
FEF ₂₅₋₇₅	M	W	2.7006	-0.04995	0	0.00010345	0.00005294
	M	B	2.1477	-0.04238	0	0.00010461	0.00004819
	M	H	1.7503	-0.05018	0	0.00014473	0.00009020
	F	W	2.3670	-0.01904	-0.000200	0.00006982	0.00002302
	F	B	2.0828	-0.03793	0	0.00008572	0.00003380
	F	H	1.7456	-0.01195	-0.000291	0.00009610	0.00004594

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Use the following equation to calculate the predicted value for a lung function parameter (LFP).

$$LFP = b_0 + b_1 * Age + b_2 * Age^2 + b_3 * Height^2$$

Height is in centimeters and age is in years. Use b_3 coefficient from the Ht_{prd} column for the predicted value calculation. Use the b_3 coefficient from the Ht_{lin} column to calculate the LLN.

The following table presents the predicted values for $FEV_{1.0}/FEV_{6.0}$ % and $FEV_{1.0}/FVC$ %

Parameter	Sex	Race	Intercept _{prd}	Age	Intercept _{lin}
			B_0	b_1	b_0
$FEV_{1.0}/FEV_{6.0}$ %	M	W	87.340	-0.1382	78.372
	M	B	88.841	-0.1305	78.979
	M	H	89.388	-0.1534	80.810
	F	W	90.107	-0.1563	81.307
	F	B	91.229	-0.1558	81.396
	F	H	91.664	-0.1670	83.034
FEV_1/FVC %	M	W	88.066	-0.2066	78.388
	M	B	89.239	-0.1828	78.822
	M	H	90.024	-0.2186	80.925
	F	W	90.809	-0.2125	81.015
	F	B	91.655	-0.2039	80.978
	F	H	92.360	-0.2248	83.044

Use the following equation to calculate the lung function parameter (LFP).

$$LFP = b_0 + b_1 * Age$$

Use the b_1 coefficient from the Intercept_{prd} column to calculate the predicted value. Use the b_1 coefficient from the Intercept_{lin} column to calculate the lower limit of normal.

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Morris - Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}	Source
FVC	M	W	20-84	$.0583H - 0.025A - 4.24$	0.74	1.22	Ref. 12
	F	W	20-84	$.0453H - 0.024A - 2.85$	0.52	0.855	Ref. 12
FEV ₁	M	W	20-84	$.0362H - 0.032A - 1.265$	0.55	0.905	Ref. 12
	F	W	20-84	$.0350H - 0.025A - 1.93$	0.47	0.773	Ref. 12
FEF _{25-75%}	M	W	20-84	$0.0185H - 0.045A + 2.513$	1.12	1.84	Ref. 12
	F	W	20-84	$0.0236H - 0.030A + 0.551$	0.80	1.316	Ref. 12

Notes:

1. The height ranges are as follows:

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	20-84	147.3-203.2	58-80
Female	20-84	142.2-182.9	56-72

IQmark Digital Spirometer Operation Manual

Roca - Adult

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}
FVC	M	W	20-69	$0.0678H - 0.0147A - 6.0548$	0.53	0.872
	F	W	20-69	$0.0454H - 0.0211A - 2.8253$	0.403	0.663
FEV ₁	M	W	20-69	$0.0499H - 0.0211A - 3.837$	0.44	0.724
	F	W	20-69	$0.0317H - 0.025A - 1.2324$	0.307	0.505
FEV ₁ /FVC%	M	W	20-69	$-0.1902A + 85.58$	5.36	8.82
	F	W	20-69	$-0.224A - 0.1126W + 94.88$	5.31	8.73
FEF _{25-75%}	M	W	20-69	$0.0392H - 0.043A - 1.1574$	1.0	1.645
	F	W	20-69	$0.023H - 0.0456A + 1.1055$	0.68	1.12
PEF	M	W	20-69	$0.0945H - 0.0209A - 5.7732$	1.47	2.42
	F	W	20-69	$0.0448H - 0.0304A + 0.3496$	1.04	1.71
FEF _{75%}	M	W	20-69	MEF75% = $A \text{LOG}(2.113 \text{Log}(H) - 0.01A - 4.136)$	0.146	0.240
FEF _{75%}	F	W	20-69	MEF75% = $A \text{LOG}(1.209 \text{Log}(H) - 0.006A - 0.001W - 2.003) - 1$	0.073	0.120
FEF _{50%}	M	W	20-69	$0.0517H - 0.0397A - 2.4$	1.3	2.14
(MEF _{50%})	F	W	20-69	$0.0242H - 0.0418A + 1.6151$	0.925	1.52

I. Reference Values - Pediatric

The IQmark Digital Spirometer software provides the following sets of reference equations for pediatric patients.

1. Knudson (1976 & 1983 compilation)
2. Polgar (1971)
3. Hsu
4. NHANES III
5. Zapletal

IQmark Digital Spirometer Operation Manual

Knudson - Pediatric

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	95% CI	Source
VC	M/F	W	All	Predicted VC = Predicted FVC			
FVC	M	W	6 - 12	0.0409H - 3.3756	0.3503	0.576	Ref. 13
	M	W	12 - 18	0.0590H + 0.0739A - 6.8865	0.4708	0.774	“
	F	W	6 - 11	0.0430H - 3.7486	0.3728	0.613	“
	F	W	11 - 20	0.0416H + 0.0699A - 4.4470	0.4973	0.818	“
FEV _{0.5}	M	W	6 - 18	0.030H + 0.043A - 3.054	0.425	0.699	Ref. 14
	F	W	6 - 18	0.019H + 0.061A - 1.738	0.364	0.599	“
FEV ₁	M		6 - 12	0.0348H - 2.8142	0.2734	0.449	Ref. 13
	M		12 - 18	0.0519H + 0.0636A - 6.1181	0.4458	0.733	“
	F		6 - 11	0.0336H - 2.7578	0.2697	0.444	“
	F		11 - 20	0.0351H + 0.0694A - 3.7622	0.4223	0.695	“
FEV ₁ /FVC%	M		6 - 18	-0.0813H + 100.4389	6.5752	10.82	Ref. 13
	F		6 - 20	-0.1909H + 0.6655A + 109.9739	7.8385	12.89	“
FEF _{25-75%}	M		6 - 12	0.0338H - 2.3197	0.6263	1.03	Ref. 13
	M		12 - 18	0.0539H + 0.0749A - 6.1990	0.9861	1.62	“
	F		6 - 11	0.0220H - 0.8119	0.6568	1.08	“
	F		11 - 20	0.0279H + 0.1275A - 2.8007	0.8653	1.42	“
PEF	M		6 - 18	0.078H + 0.1660A - 8.060	1.653	2.72	Ref. 14
	F		6 - 20	0.0490H + 0.157A - 3.916	1.339	2.20	“
FEF _{25%} (MEF _{75%})	M		6 - 18	0.0700H + 0.1470A - 7.054	1.530	2.52	Ref. 14
	F		6 - 20	0.0440H + 0.1440A - 3.365	1.290	2.12	“
FEF _{50%} (MEF _{50%})	M		6 - 12	0.0378H - 2.5454	0.6538	1.08	Ref. 13
	M		12 - 18	0.0543H + 0.1150A - 6.3851	1.1196	1.84	“
	F		6 - 11	0.1846A + 0.7362	0.6689	1.10	“
	F		11 - 20	0.0288H + 0.1111A - 2.3040	0.9585	1.58	“

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FEF _{75%} (MEF _{25%})	M		6 - 12	0.0171H - 1.0149	0.5037	0.829	Ref. 13
	M		12 - 18	0.0397H - 0.0057A - 4.2421	0.7551	1.24	“
	F		6 - 11	0.0109H - 0.1657	0.4999	0.822	“
	F		11 - 20	0.0243H + 0.2923A - 4.4009 - 0.0075A ²	0.7202	1.18	“
MVV	M		6 - 18	1.840H + 1.800A - 192.3			K3
	F		6 - 19	1.090H + 3.40A - 108.1			K3

Notes:

1. Height ranges are as follows:

Sex	Age Range	Height Range (cm)	Height Range (in)
Male	6-12	111.8-154.9	44-61
Male	12-18	139.7-193.0	55-76
Female	6-11	106.7-147.3	42-58
Female	11-20	132.1-182.9	52-72

Polgar - Pediatric

See Reference 19.

Height (H) is in centimeters.

Parameter	Sex	Race	Age Range	Predicted Equation	SEE	CI _{95%}
FVC	M	W	4-17	$0.0000044 \times H^{2.67}$		
	F	W	4-17	$0.0000033 \times H^{2.72}$		
FEV _{1.0}	M	W	4-17	$0.0000021 \times H^{2.80}$		
	F	W	4-17	$0.0000021 \times H^{2.80}$		
FEV _{3.0}	M	W	4-17	$FVC_{pred} * 0.98$		
	F	W	4-17	$FVC_{pred} * 0.98$		
FEV ₁ /FVC %	M	W	4-17	$47.73 \times H^{0.13}$		
	F	W	4-17	$63.63 \times H^{0.08}$		
FEF _{25-75%}	M	W	4-17	$0.0437 \times H - 3.4616$		
	F	W	4-17	$0.0437 \times H - 3.4616$		
PEF (L/s)	M	W	4-17	$0.08738 * H - 7.0929$		
	F	W	4-17	$0.08738 * H - 7.0929$		
MVV (L/min)	M	W	4-17	$1.276 * H - 99.507$		
	F	W	4-17	$1.276 * H - 99.507$		

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Hsu - Pediatric

Parameter	Sex	Race	Age Range	Predicted Equation	SD%	Source
FVC	M	W	7-20	$3.58 \times 10^{-7} \times H^{3.18}$	13	Ref. 15
	M	B	7-20	$1.07 \times 10^{-6} \times H^{2.93}$	17	“
	M	H	7-20	$1.06 \times 10^{-6} \times H^{2.97}$	13	“
	F	W	7-20	$2.57 \times 10^{-6} \times H^{2.78}$	14	“
	F	B	7-20	$8.34 \times 10^{-7} \times H^{2.98}$	15	“
	F	H	7-20	$1.25 \times 10^{-6} \times H^{2.92}$	14	“
FEV ₁	M	W	7-20	$7.74 \times 10^{-7} \times H^{3.00}$	13	“
	M	B	7-20	$1.03 \times 10^{-6} \times H^{2.92}$	17	“
	M	H	7-20	$1.73 \times 10^{-6} \times H^{2.85}$	13	“
	F	W	7-20	$3.79 \times 10^{-6} \times H^{2.68}$	14	“
	F	B	7-20	$1.14 \times 10^{-6} \times H^{2.89}$	15	“
	F	H	7-20	$1.61 \times 10^{-6} \times H^{2.85}$	14	“
FEF _{25-75%}	M	W	7-20	$7.98 \times 10^{-7} \times H^{2.46}$	26	“
	M	B	7-20	$3.61 \times 10^{-7} \times H^{2.60}$	36	“
	M	H	7-20	$9.13 \times 10^{-7} \times H^{2.45}$	25	“
	F	W	7-20	$3.79 \times 10^{-6} \times H^{2.16}$	28	“
	F	B	7-20	$1.45 \times 10^{-6} \times H^{2.34}$	30	“
	F	H	7-20	$1.20 \times 10^{-6} \times H^{2.40}$	24	“
PEF	M	W	7-20	$3.35 \times 10^{-7} \times H^{2.79}$	18	“
	M	B	7-20	$1.74 \times 10^{-7} \times H^{2.92}$	22	“
	M	H	7-20	$7.69 \times 10^{-7} \times H^{2.63}$	17	“
	F	W	7-20	$2.58 \times 10^{-6} \times H^{2.37}$	18	“
	F	B	7-20	$5.51 \times 10^{-7} \times H^{2.68}$	20	“
	F	H	7-20	$6.97 \times 10^{-7} \times H^{2.64}$	18	“

Notes:

1. Race: W = white, B = black, H = Hispanic or Mexican-American
2. The original equations provide volume in milliliters and flow in milliliters per second. The above equations are a modification of the original equations and provide volume in liters and flow in liters per second.
3. Height (H) range is from 110.0 to 190.0 cm for male and 110.0 to 180.0 for female.

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NHANES III (Hankinson, NLHEP) – Pediatric

Parameter	Sex	Race	Intercept	Age	Age ²	Ht _{prd} (cm) ²	Ht _{lln} (cm) ²
			b ₀	b ₁	b ₂	b ₃	b ₃
FVC	M	W	-0.2584	-0.20415	0.010133	0.00018642	0.00015695
	M	B	-0.4971	-0.15497	0.007701	0.00016643	0.00013670
	M	H	-0.7571	-0.09520	0.006619	0.00017823	0.00014947
	F	W	-1.2082	0.05916	0	0.00014815	0.00012198
	F	B	-0.6166	-0.04687	0.003602	0.00013606	0.00010916
	F	H	-1.2507	0.07501	0	0.00014246	0.00011570
FEV _{1.0}	M	W	-0.7453	-0.04106	0.004477	0.00014098	0.00011607
	M	B	-0.7048	-0.05711	0.004316	0.00013194	0.00010561
	M	H	-0.8218	-0.04248	0.004291	0.00015104	0.00012670
	F	W	-0.8710	0.06537	0	0.00011496	0.00009283
	F	B	-0.9630	0.05799	0	0.00010846	0.00008546
	F	H	-0.9641	0.06490	0	0.00012154	0.00009890
FEV _{6.0}	M	W	-0.3119	-0.18612	0.009717	0.00018188	0.00015323
	M	B	-0.5525	-0.14107	0.007241	0.00016429	0.00013499
	M	H	-0.6646	-0.11270	0.007306	0.00017840	0.00015029
	F	W	-1.1925	0.06544	0	0.00014395	0.00011827
	F	B	-0.6370	-0.04243	0.003508	0.00013497	0.00010848
	F	H	-1.2410	0.07625	0	0.00014106	0.00011480
PEF	M	W	-0.5962	-0.12357	0.013135	0.00024962	0.00017635
	M	B	-0.2684	-0.08016	0.018202	0.00027333	0.00018938
	M	H	-0.9537	-0.19602	0.014497	0.00030243	0.00021833
	F	W	-3.6181	0.60644	-0.016846	0.00018623	0.00012148
	F	B	-1.2398	0.16375	0	0.00019746	0.00012160
	F	H	-3.2549	0.47495	-0.013193	0.00022203	0.00014611
FEF ₂₅₋₇₅	M	W	-1.0863	0.13939	0	0.00010345	0.00005294
	M	B	-1.1627	0.12314	0	0.00010461	0.00004819
	M	H	-1.3592	0.10529	0	0.00014473	0.00009020
	F	W	-2.5284	0.52490	-0.015309	0.00006982	0.00002302
	F	B	-2.5379	0.43755	-0.012154	0.00008572	0.00003380
	F	H	-2.1825	0.42451	-0.012415	0.00009610	0.00004594

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Use the following equation to calculate the predicted value for a lung function parameter (LFP).

$$LFP = b_0 + b_1 * Age + b_2 * Age^2 + b_3 * Height^2$$

Height is in centimeters and age is in years. Use b_3 coefficient from the Ht_{prd} column for the predicted value calculation. Use the b_3 coefficient from the Ht_{lin} column to calculate the lower limit of normal.

The following table presents the predicted values for FEV_{1.0}/FEV_{6.0} % and FEV_{1.0}/FVC %

Parameter	Sex	Race	Intercept _{prd}	Age	Intercept _{lin}
			B_0	b_1	b_0
FEV _{1.0} / FEV _{6.0} %	M	W	87.340	-0.1382	78.372
	M	B	88.841	-0.1305	78.979
	M	H	89.388	-0.1534	80.810
	F	W	90.107	-0.1563	81.307
	F	B	91.229	-0.1558	81.396
	F	H	91.664	-0.1670	83.034
FEV _{1.0} / FVC %	M	W	88.066	-0.2066	78.388
	M	B	89.239	-0.1828	78.822
	M	H	90.024	-0.2186	80.925
	F	W	90.809	-0.2125	81.015
	F	B	91.655	-0.2039	80.978
	F	H	92.360	-0.2248	83.044

Use the following equation to calculate the lung function parameter (LFP).

$$LFP = b_0 + b_1 * Age$$

Use the b_1 coefficient from the Intercept_{prd} column to calculate the predicted value. Use the b_1 coefficient from the Intercept_{lin} column to calculate the lower limit of normal.

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Zapletal - Pediatric

Age range is from 6 to 18 years. Height (H) is in centimeters.

Parameter	Sex	Race	Predicted Equation	SEE	CI _{95%}
FVC	M	W	$7.9942 - 0.12509 \times H + 0.000605 \times H^2$		
	F	W	$0.1694 - 0.01217 \times H + 0.000605 \times H^2$		
FEV _{1.0}	M	W	$6.6314 - 0.10261 \times H + 0.000499 \times H^2$		
	F	W	$-3.0378 + 0.03640 \times H$		
FEF _{25%}	M	W	$-2.3069 + 0.02817 \times H$		
	F	W	$-1.8576 + 0.02483 \times H$		
FEF _{50%}	M	W	$-4.5848 + 0.05430 \times H$		
	F	W	$-3.3655 + 0.04477 \times H$		
FEF _{75%}	M	W	$-6.822 + 0.07811 \times H$		
	F	W	$-5.1934 + 0.06367 \times H$		
PEF	M	W	$-6.9865 + 0.08060 \times H$		
	F	W	$-5.3794 + 0.06594 \times H$		

J. Adjustments to Reference Values Equations

According to the ATS recommendations specified in Reference 2 and studies cited by Enright (Reference 23), Black and Asian adults have FVC and FEV₁ values that are approximately 15% below that of Caucasians. Black children have FVC and FEV₁ values that are approximately 12% lower than Caucasian children's values.

The software makes the following adjustments to the reference values for Asian and Black patients if the reference equations are only for a white patient population.

Correction Of Reference Values For Blacks And Asians

Measurement	Scale Factor
FEV ₁	0.85
FVC	0.85
FEV ₁ /FVC %	None

Correction Of Reference Values For Black Children

Measurement	Scale Factor
FEV ₁	0.88
FVC	0.88
FEV ₁ /FVC %	None

The software does not use the above correction factors if the reference equations in use include the patient's race, e.g., Hankinson.

Not all race scale factors have been documented. At the time of this printing, many races have had some published recommendations. The latest recommendations are as follows:

1.00 - American Indian, Caucasian, Eskimo, European-American, Hawaiian, Hispanic, Indian, Italian, Iranian, Jordanian, Polynesian, Saudi Arabian, South American, Spanish, White

0.85 - Asian, African, African-American, Black, Cambodian, Chinese, East Indian Pakistani, Filipino, Jamaican, Japanese, Korean, Laotian, Vietnamese

However, a recent paper by Korotzer et al (Am. J. Respir. Crit. Care Med. 2000 161: 1101-1108) suggests a **0.93** correction for Asian-American.

K. Glossary

ARCHIVING	Placing data into storage where it cannot be damaged or altered. Archived data, such as spirometer reports, can be retrieved at a later date for review.
IQMARK DIAGNOSTIC WORKSTATION (DIAGNOSTIC WORKSTATION)	The name of the software application you install on your IBM compatible computer in order to use the Spirometer.
BTPS	Body conditions; normal body Temperature (37°C); ambient Pressure; Saturated with water vapor.
CLICK	In this manual, Click refers to tapping a mouse button once – quickly and firmly. For example, if you want to pull down the Medications list, you will click on the list name. Double Click refers to performing this task twice, and is generally used to start programs.
DATABASE	A collection of data arranged into methodically organized categories. In this manual, the term refers to the collection of reports that the Diagnostic Workstation will store on your hard drive.
DESKTOP	The background that appears on your computer screen behind the application windows.
DIALOG BOX	An on-screen form you complete to provide the Diagnostic Workstation with information that it needs to accomplish a task, such as the Medications window.
ECG	See electrocardiogram.
ELECTROCARDIOGRAM	A graphic recording that displays the electrical activities of the heart. Contact Brentwood for additional information.
FOLDER	Folders, which function like the drawers in a filing cabinet, are used by Windows to organize files and applications. The Diagnostic Workstation application resides in a folder named “Brentwood”, which is located in your hard drive.

IQmark Digital Spirometer Operation Manual

IBM COMPATIBLE	Any computer that functions like an IBM PC, but is not manufactured by IBM. Compatibles can use the same software and peripheral devices as IBM PC's, and can run Microsoft Windows. The Spirometer requires an IBM PC or an IBM compatible PC, installed with Windows, for operation.
MY COMPUTER	A Windows icon that appears on the desktop in the form of a stylized computer. Clicking on My Computer enables you to explore your computer's disks, printers, Control Panel, etc.
PORT	A place where data is passed in and out of a computer. IBM compatible PCs, typically have several ports located on the back panels of the computer. The Spirometer communicates the data it collects from patients, through a serial port located on this back panel.
PREDICTED VALUES	Also known as Reference Values or Predicted Equations Sets. A value for a parameter is calculated and estimated as "normal" for the age, height, sex, and sometimes the ethnic background of the patient. These values are compared to a patient's actual values to evaluate a patient's lung condition.
SERIAL PORT	A 9- and/or 25- pin port that is used by a computer to communicate serial data, typically labeled COM1 or COM2. The Spirometer connects to a 9-pin serial port or a 25-pin serial port if an adapter is used. Consult your computer owner's manual for more information on configuration and capability.
SHORTCUT ICON	Generally appearing on the desktop, shortcut icons enables you to open a document, application, or folder simply by double clicking on them.
SPIROMETER	Brentwood's Module for converting an IBM compatible PC into a spirometer with interpretive capability. The Spirometer is operated using the Diagnostic Workstation software application.
START BUTTON	Appears at the left end of the Windows Taskbar, and enables you to start applications, open files, get to the Control Panel and exit Windows. Consult your Windows owners' manual for more information.

TASKBAR	A gray bar that typically appears at the bottom of the screen. In Windows, the Taskbar provides rapid access to the Start Button and open applications. The Diagnostic Workstation requires the taskbar be set to Auto hide in order for it to work properly.
TEXT BOX	A box where you type in text relative to an application or task. Select the text box by clicking in it and start typing.

L. Spirometry Parameters Measured and Defined

FVC	FEV _{0.5}	FEV _{1.0}	FEV _{3.0}	FEV _{6.0}	FEV _{1.0} /FVC	FEV _{3.0} /FVC	FEV _{1.0} /FEV _{6.0}
FEV _{25%}	FEV _{50%}	FEV _{75%}	FEV _{25-75%}	FEV _{75-85%}	FEV ₂₀₀₋₁₂₀₀		FEV _{0.5} /FIV _{0.5}
PEF	FIVC	FIV _{0.5}	FIF _{50%}	PIF		Exp Time	V ext.
MVV	RR	AT	AT%	VC	ERV	IRV	TV

Unless otherwise noted: Volumes (capacity) are expressed in Liters BTPS (L)
 Flows are expressed in Liters per second BTPS (L/s)

AT – Air Trapping – Calculated if an accepted FVC and an accepted VC test is saved in the same session. Displayed in Liters, it is the difference of the VC and the FVC.

AT% – Air Trapping Percentage – Calculated if an accepted FVC and an accepted VC test is saved in the same session. Displayed as a percentage it is the difference of the VC and the FVC divided by the VC.

FVC – **Forced Vital Capacity** – The total volume of air exhaled during a forced expiration (maximally forced effort) starting from a position of full inspiration and ending at complete expiration. Expiration must be made as forcefully and completely as possible. A decrease in FVC is common to restrictive disorders and severe obstructive disease.

FEV_X – **Forced Expiratory Volume** at X (0.5, 1.0, 3.0, 6.0) second(s) – The volume of air exhaled during a set value of time. The FEV at the first second of the FVC maneuver is the most common. Back extrapolation is used to determine the beginning of the FVC maneuver. A decrease in the FEV₁ value is common in obstruction of large to mid-sized airways.

FEV_{1.0} / FVC – Ratio of the volume of air expired in one second to the total volume of air expired during the FVC test. An obstruction can cause a decrease in this ratio.

FEV_{3.0} / FVC – Ratio of the volume of air expired in three seconds to the total volume of air expired during the FVC test.

FEV_{1.0} / FEV_{6.0} – Ratio of the volume of air expired in one second to the total volume of air expired in six seconds during the FVC test.

FEF_{XX%} – **Forced Expiratory Flow** where XX could be 25, 50 or 75. This is the expiratory flow rate at a certain percentage of the total FVC.

FEF_{25-75%} – **Forced Expiratory Flow** from 25% of expiration to 75% of expiration, the middle half of the FVC. Also known as the MMEF (maximal mid-expiratory flow). Decreases can be an indicator of early stages of lung disease.

FEF_{75-85%} – **Forced Expiratory Flow** from 75% of expiration to 85% of expiration.

FEF₂₀₀₋₁₂₀₀ – **Forced Expiratory Flow** from 200 mL of expiration to 1200 mL of expiration. Mostly used in the European Union.

FEV_{0.5} / FIV_{0.5} – Ratio of the volume of air expired in one-half second to the total volume of air inspired in one-half second during the FV loop test.

PEF - Peak Expiratory Flow – Largest expiratory flow achieved with a maximally forced effort from a position of maximal inspiration. Also known as **PEFR (Rate)** in spirometry or just **PF (Peak Flow)** in monitoring devices.

FIVC – Forced Inspiratory Vital Capacity – The volume of air inhaled from a position of full expiration to full inspiration.

FIV_{0.5} – **Forced Inspiratory Volume** at one-half second after the start of inspiration.

FIF_{50%} – **Forced Inspiratory Flow** at 50 percent of inspiration.

PIF – Peak Inspiratory Flow – The maximum inspiratory flow rate measured during the forceful inspiratory portion of the FV Loop.

Exp time – Total expiratory time for the forced expiratory maneuver.

V ext – Volume of air from the beginning of expiration to the zero point of the FVC due to back extrapolation.

MVV – Maximal Voluntary Ventilation – The volume of air expired with continual maximal expiration and inspiration measured over a 12 second duration. Volumes are then extrapolated to one minute.

RR – Respiration Rate – The respiration frequency (Liters/Breath) measured during a MVV maneuver.

VC – Vital Capacity – The maximum volume of air exhaled from the point of maximal inhalation or the maximal volume of air inhaled from a point of maximal exhalation can be measured with a slow exhalation or inhalation, respectively. It is the volume change at the mouth between the positions of full inspiration and complete expiration. Previously called the “slow” vital capacity (SVC).

ERV – Expiration Reserve Volume – The volume of air that can be expired by a forceful expiration after the end of a normal tidal expiration.

IRV – Inspiration Reserve Volume – The volume of air that can be inspired by a forceful inspiration after the end of a full expiration.

TV – Tidal Volume – The volume of air inspired and expired with each normal breath.

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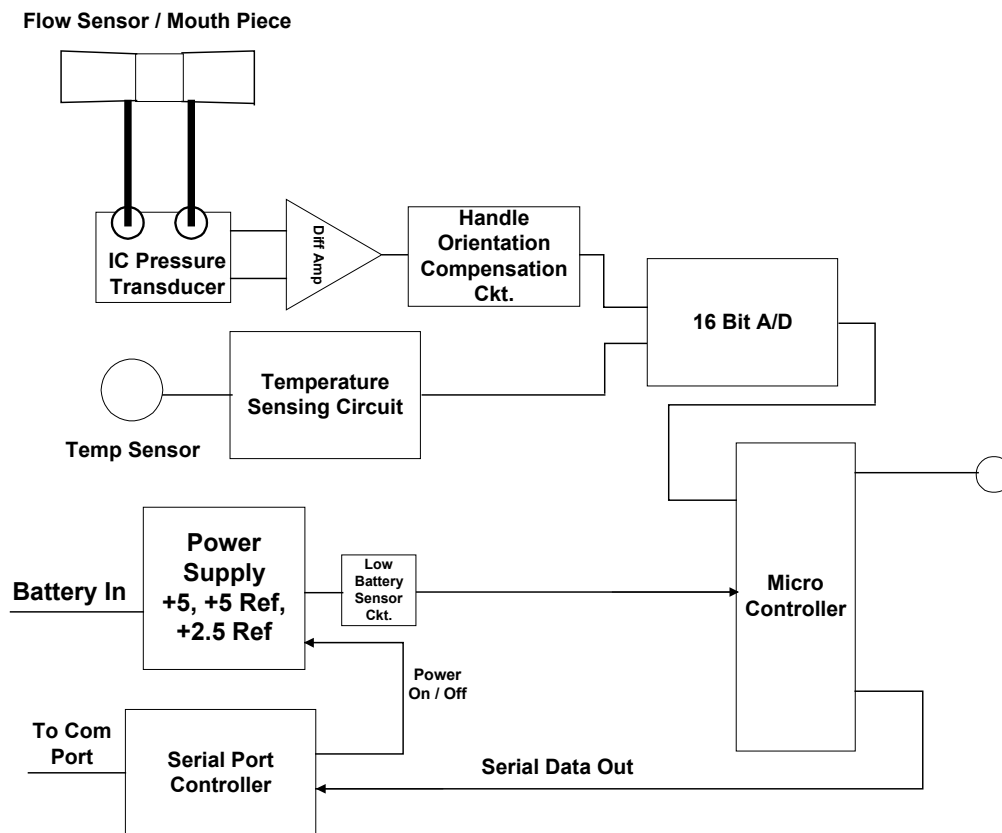
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N. Technical Service Manual

Service Manual Introduction

The IQmark Digital Spirometer is a PC based diagnostic instrument that converts an IBM compatible personal computer to a diagnostic Spirometer with interpretative and data storage capabilities. A complete IQmark Digital Spirometry system usually consists of the Spirometer data acquisition module (handle), the PC system, which includes a monitor and a printer, one of the Microsoft Windows operating systems (Windows 95, Windows 98, Windows Me, Windows NT 4.0, and Windows 2000), and the Brentwood Workstation software program. Additional testing modalities such as the IQmark Digital ECG and Vital Statistics acquisition devices can be incorporated simultaneously utilizing the IQmark Diagnostic Workstation software.

This section is provided to assist with the troubleshooting of some commonly experienced problems and service of the IQmark Digital Spirometer data acquisition module. For information regarding the service and operation of the PC system you have selected, consult the documents provided by your PC manufacturer.



Block Diagram

Theory of Operation

The IQmark Digital Spirometer Handle or data acquisition module is a self contained module for the acquisition and digitalization of pressure data acquired via the DPM. The IQmark Digital Spirometer operating principals are that of the Fleisch Pneumotach.

The Disposable Pneumotach Mouthpiece

The Pneumotach, also known as the flow sensor, mouthpiece or DPM, is a single piece low cost disposable device. Its primary components are the pressure ports, mouthpiece and laminar flow element (LFE). During pulmonary function testing (PFT) air is expelled and travels through the LFE. The LFE smooths the air flow and provides a consistent resistance in the path of the air. Two pressure ports sense pressure changes on either side of the LFE. The pressure ports are connected to a precision differential pressure transducer. The differential pressure signal is digitalized and sent via the serial port to the Spirometry program running on the PC. The Spirometry program computes flow using the pressure data then calculates volume by integrating flow data over time.

IC Pressure Transducer

A precision piezoelectric transducer takes differential pressure measurements from the disposable pneumotach mouthpiece. Differential measurements produce more accurate results as opposed to comparing a single measurement to estimated ambient air pressure.

Handle Orientation Compensation Circuit (Ckt.)

An orientation compensation circuit stabilizes the Spirometer during PFT testing. This circuit eliminates artifacts generated by motion in the X, Y and Z axis as well as allowing a short enclosed hose path from the pneumotach to the transducer.

16 bit A/D

The A/D converter used is a programmable 2 channel Sigma Delta 16 bit A/D converter. The A/D converter provides the 12Hz low pass filtering for the Spirometry pressure signal. The effective sampling rate is 48 Hz. The digitized pressure signal is sent serially to the micro controller.

Temperature Sensor

An LM34 temperature sensor relays ambient temperature information to the Spirometer program. Ambient temperature is utilized to produce more accurate BTPS calculations. The A/D converter converts the temperature signal when the Spirometer handle is powered up and then passes it along to the Spirometer program through the micro controller and serial interface.

Micro controller

The micro controller is a PIC16C66 chip produced by Microchip Technology. The micro controller receives the digitized data from the A/D converter, temperature sensor, low battery detection circuit, and identification device and encodes the data with packets and sends it to the PC through the RS232 interface circuit.

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Serial port controller

The serial signal sent out by the PIC micro controller is relayed to the system through the MAX3232CSE RS-232 transceiver. To provide the maximum safety for the patient the Spirometer hardware and the PC are isolated via double insulation.

Power Supply

The IQmark Digital Spirometer uses two AAA batteries for power. A step up DC-DC converter is used to provide a 6.2 V power source. Two 5.0 V regulators are used to provide power sources for the analog and digital circuits. A 2.5 V reference voltage is derived with a voltage divider and current amplifier to provide the Spirometer's pressure signal baseline and A/D reference voltage. The IQmark Digital Spirometer's power is switched ON or OFF by software control via the DTR bit of the RS232 port.

Low Battery Sensor Circuit

The low battery detection circuit monitors the battery voltage and alerts the micro controller when the energy in the batteries is low. The micro controller causes the LED in the handle to glow RED and sends a LOW BATTERY message that is displayed on the screen by the Spirometer software. The user can complete the current testing session with confidence but should replace the batteries before starting a new test session.

System Maintenance and Obtaining Service

The IQmark Digital Spirometer is a battery powered, portable device, which requires little maintenance and contains no user adjustable or serviceable components inside. There are no fuses in the Spirometer handle. In the event that the Spirometer hardware does not appear to function correctly and the remedies offered in the troubleshooting guide do not correct the problem, contact Brentwood Customer Support. In the event that Repairs are required our staff will provide complete instructions on returning the Spirometer.

DO NOT send your Spirometer without first contacting a Customer Support representative. A return authorization is required prior to the return of the device. Help us to service you better and minimize your down time. Obtain a Return Goods Authorization (RGA) number prior to returning your Spirometer.

Brentwood Medical Technology Corp.
3300 Fujita Street
Torrance, CA 90505
Tel: (310) 530-5955
Fax:(310) 530-1421

To obtain optimum benefits and to ensure the best performance of this device, the user should read and understand all information offered in this Operation Manual.

- (1) For the greatest accuracy, calibrate the Spirometer frequently. Daily calibration is recommended by the ATS.
- (2) DO NOT RE-USE Disposable Pneumotach Mouthpieces.

IQmark Digital Spirometer Operation Manual

- (3) Replace the batteries when the device LED turns Red or the computer screen displays the “low battery” indication.
- (4) Inspect the Spirometer periodically for accuracy. Contact Brentwood for your annual calibration certifications.

Troubleshooting

Problem	Cause	Solution
Volume numbers appear too high or too low	1. Ambient air pressure or temperature has changed since the last calibration. 2. The current lot of pneumotachs is slightly different from the last lot. 3. The “Use Dry Air Conditions” option was checked.	1. Calibrate the Spirometer. 2. Calibrate the Spirometer. 3. De-select the “Use Dry Air Conditions” option when performing patient tests. This option disables the BTPS corrections.
FVC Test Starts for no reason	1. The minimum flow required to start a test has been exceeded. 2. Excessive electromagnetic interference is affecting the instrument.	1. Instruct the patient not to move the handle abruptly, which can cause air to flow through the pneumotach and start a test. Turn off fans or close heating and air conditioning vents near the test area. Close doors or windows. Delay pressing the “Start New Test” button until just prior to beginning the maneuver. 2. Select a different location or find and correct the source of the interference. Contact Brentwood Customer Support for additional assistance.

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Can Not Zero Spirometer handle	1. Air is flowing through the pneumotach while the software is attempting to zero the Spirometer. 2. Excessive electromagnetic interference is affecting the instrument.	1. Instruct patient exactly when to blow. 2. Select a different location or find and correct the source of the interference. Contact Brentwood Technical support.
LED on handle glows or flashes Red	1. Batteries are low	1. Replace with new batteries.
LED on handle glows or flashes Red even after new batteries have been installed	1. The Com port is not communicating with the handle. 2. The Com port can not drive the Spirometer. 3. The Spirometer is defective.	1. Configure the Com port. 2. Repair computer Com port 3. Call Brentwood for RGA. Repair Spirometer.
LED on handle will not turn on.	1. No batteries installed in the handle. 2. The handle is not plugged into an available Com port 3. The Com port is not talking with the handle. 4. If after steps 1-3, LED does not turn on, Spirometer is defective	1. Install new batteries 2. Plug Spirometer into an available Com port. 3. Configure the Com port. 4. Call Brentwood for RGA, Repair Spirometer.
LED will not turn ON, unit functions correctly.	1. Defective LED	Call Brentwood for RGA, Repair Spirometer.
LED on handle will not turn OFF but unit functions correctly otherwise.	1. Com port is defective. 2. Com port not compatible with Spirometer. 3. Installed USB to Serial port converter is not compatible with the Spirometer.	1. Repair Com port 2. Install USB Com Port. Contact Brentwood Technical support 3. Install different USB to Serial Port converter. Contact Brentwood Technical support.
Battery door will not close	1. Battery contact damaged.	1. Call Brentwood for RGA, Repair Spirometer.
Can not install Pneumotach into Spirometer	1. Leur fitting (pressure port) plugged with plastic from last pneumotach.	1. Carefully remove plastic from Leur fitting.

O. Performing a FVC Test - Quick Reference User's Guide

- 1) Start the **Diagnostic Workstation** program - double click on the Workstation icon.
- 2) Select the patient. Either click on **New Patient** and enter the appropriate information or **Patient File** (for an existing patient) and double click on the appropriate patient name.
- 3) Check the patient data fields on the screen. Remember that the R.A.S.H. (Race; Age; Sex; Height) must be entered for each patient to obtain predicted values and interpretations.
- 4) When the Patient Data screen is complete, click **New Test**.
- 5) Select **Spirometry** and then click **OK** to enter the test screen.
- 6) Prepare the patient for the spirometry test.
 - a) Explain the procedure to the patient
 - b) Demonstrate the procedure to the patient
 - c) Instruct the patient to select a new disposable mouthpiece and to insert it into the handle
 - d) Instruct the patient to place the mouthpiece on top of their tongue, with their teeth and lips around the mouthpiece. The patient must seal the outer part of the mouthpiece with their lips. Let the patient get used to the feeling of breathing with the mouthpiece in their mouth.
- 7) When the patient is ready, instruct the patient to hold the handle close to but not in front of their mouth. Be sure that the patient is not breathing through the mouthpiece when you start the test.
- 8) Click on **Start New Test** - wait for the zeroing process – **DO NOT ALLOW AIRFLOW TO PASS THROUGH THE MOUTHPIECE DURING THIS PROCESS.**
- 9) When the incentive box displays “Start When Ready” instruct the patient to perform a full inspiration and then to place the mouthpiece in their mouth. Instruct the patient to Blast out the air. Encourage the patient with verbal and body language to blast out fast and blast out long. Ask the patient to continue to blow out until a plateau is reached on the volume-time curve. If a flow volume loop is required, have the patient inhale at the end of the expiration.
- 10) Click the **Stop** button or press the ENTER key to conclude the test. Accept or Reject the test based on the patient's effort. Repeat steps 7 through 9 until the appropriate number of tests has been performed. Performing more than 8 forced vital capacity tests in one sitting will usually return diminished results.
- 11) Click the **Save/Review** button and click **Yes** to save the efforts. Use the review screen to review, edit and/or print the results.
- 12) Instruct the patient to remove and discard the used mouthpiece after all tests are completed.

P. Performing a Pre/Post FVC Test - Quick Reference User's Guide

TESTING ONE PATIENT AT A TIME

- 1) Start the **Diagnostic Workstation** program - double click on the Workstation icon.
- 2) Select the patient and check the patient data fields on the screen or add a new patient. Remember that R.A.S.H. (Race; Age; Sex; Height) must be entered to obtain predicted values and interpretations.
- 3) Click on **New Test**.
- 4) Click on **Spirometry** and then click on **OK** to enter the test screen.
- 5) Prepare the patient for the spirometry test.
- 6) When the patient is ready, click on **Start New Test**.
- 7) Wait for the zeroing process and instruct the patient to perform the test.
- 8) Click the **Stop** button or press the ENTER key to conclude the test. Accept or Reject the test based on the patient's effort. Repeat steps 6 and 7 until the appropriate number of tests has been performed.
- 9) Click the **Save/Review** button and click **Yes** to save the efforts. Use the review screen to review, edit and/or print the results.
- 10) Administer the bronchodilator (BD). Wait the appropriate amount of time for the BD to take effect.
- 11) Select the correct BD from the **Bronchodilator** list and click the **Perform Post-BD** button. Click on **Yes** to save the addition of the BD to the report.
- 12) Repeat steps 5 through 9.
- 13) Instruct the patient to remove and discard the used mouthpiece after all tests are completed.
- 14) Review the Interpretation, edit if desired, then click **Print** and choose **Print**.

Q. Performing a Pre/Post FVC Test – Quick Reference User's Guide

TESTING MULTIPLE PATIENTS

- 1) Start the **Diagnostic Workstation** program - double click on the Workstation icon.
- 2) Select a patient and check the patient data fields on the screen or add a new patient. Remember that R.A.S.H. (Race; Age; Sex; Height) must be entered to obtain predicted values and interpretations.
- 3) Click the **New Test** button.
- 4) Select **Spirometry** and then click **OK** to enter the test screen.
- 5) Prepare the patient for the spirometry test.
- 6) When the patient is ready, click **Start New Test**.
- 7) Wait for the zeroing process to finish and then instruct the patient to perform the test.
- 8) Click the **Stop** button or press the ENTER key to conclude the test. Accept or Reject the test based on the patient's effort. Repeat steps 6 and 7 until the appropriate number of tests has been performed.
- 9) Click the **Save/Review** button and select **Yes** to save the efforts. Use the review screen to review, edit and/or print the results.
- 10) Administer the bronchodilator (BD). Wait the appropriate amount of time for the BD to take effect. Instruct the patient to remove the mouthpiece and to hold on to it until after all tests are completed.
- 11) Click the **Patient List** button. Select the next patient. Click on **Yes** to save modifications.
- 12) Repeat steps 2 through 11 for the next patient.
- 13) Select the first patient from the Patient List and click the **View Report** button.
- 14) Select a BD from the **Bronchodilator** list and click the **Perform Post-BD** button.
- 15) Have the patient place the mouthpiece in the spirometry handle. Repeat steps 5 through 9.
- 16) Instruct the patient to remove and discard the used mouthpiece after all tests are completed. Review the Interpretation, edit if desired, then click **Print** and choose **Print**.
- 17) Repeat steps 11 through 16 for the next patient.

R. Customer Support and Brentwood Telephone Numbers

For help in diagnosing problems with this product, refer to the online help for immediate assistance. You can also contact Brentwood Customer Support at (310) 530-5955, ext 2. Inside the Continental United States, contact Customer Support at (800) 624-8950, ext 2. Office hours are 9:00 AM- 5:00 PM, Pacific Standard Time (PST).

Warranty

All Brentwood Products are warranted free from manufacturing and material defects for 12 months from the date of purchase. Any misuse or abuse of the product voids all warranties.

Return Goods Authorization

To return any product for repair, an RGA (Return Goods Authorization) number must be obtained from Brentwood Customer Support. This number should be referenced on the package(s) containing the items to be returned and in any correspondence regarding the return.

Shipping

Before shipping any unit to Brentwood, be certain that an RGA (Return Goods Authorization) number has been issued and that all guidelines regarding this authorization are followed. We highly recommend that you follow all guidelines for the shipment of a medical product set forth by the shipping company of your choice. If a question should arise regarding an appropriate method of shipment, please feel free to ask when calling for your Return Goods Authorization Number. It is ultimately the responsibility of the customer when shipping a product to ensure that all packages and their contents get to Brentwood safely.

Brentwood will not assume any responsibility for damage due to improper packaging, shipment or use of a product. Such actions will also result in all warranties being void. It is the customer's responsibility to ensure proper packaging and shipment of the product. Packaging and shipping costs associated with the return of the product to Brentwood are also the customer's responsibility.